U.S. Department
of Transportation

**Federal Aviation
Administration**

Aircraft Certification Systems Evaluation Program (ACSEP) FY 1997 Report

Prepared by
Aircraft Certification Service

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EXECUTIVE SUMMARY

This report documents the fiscal year (FY) 1997 results of the Federal Aviation Administration (FAA) Aircraft Certification Service (AIR) Aircraft Certification Systems Evaluation Program (ACSEP).

The ACSEP was designed to determine if FAA production approval holders, their priority parts suppliers, and delegated facilities are complying with the requirements of applicable Federal Aviation Regulations (FAR) and the procedures established to meet those requirements. It also surveys the application of standardized industry practices not required by the FAR or FAA-approved data to identify national trends that may require development of new or revised regulations, policy, or guidance. The elements of the evaluation are referred to as criteria. Data was collected on noncompliance and applicability with respect to those criteria. The history and background of ACSEP, the structure of the evaluation teams, and departmental interactions are discussed in *Appendix A*.

During an ACSEP evaluation, the actual operating practices of a facility are compared to the FAR, FAA-approved data, and the facility's internal procedures. Any inconsistency discovered (termed "issue" in this report) is classified and recorded. An issue is classified by its type and the subsystem under which it is noted. There are five issue types:

Safety Finding - an issue that compromises immediate continued operational safety.

Systemic Finding - an issue that is systemic in nature, i.e., is pervasive, repeatable, or represents a breakdown in the quality management system. For an issue to be categorized a finding, it must also be a noncompliance to a FAR or FAA-approved data (or noncompliances with the procurement instrument when a facility is a supplier).

Systemic Observation - an issue that is systemic in nature and is a noncompliance to facility procedures that are not FAA approved.

Isolated Observation - an issue that is of an isolated or nonsystemic nature, i.e., isolated to a particular person and/or timeframe and does not represent a breakdown in the quality management system. For an issue to be categorized an isolated observation, it must also be an isolated noncompliance to a FAR or FAA-approved data (or a noncompliance with the procurement instrument when a facility is a supplier).

FAR-Based Observation - the discovery of FAA-approved data that is inconsistent with the FAR.

The second form of classification of an issue is the subsystem under which it is discovered. In total, there are 17 subsystems that represent a quality management system:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAR Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

Each subsystem is further divided into "criteria." The criteria were developed with extensive assistance from industry in order to fully represent the detailed areas within each of the 17 subsystems. A process also exists to identify potential new criteria should the existing criteria not address a particular functional area within a subsystem. The subclassification of issues into the detailed criteria allows the FAA to identify specific areas of concern and allows industry to focus corrective action on these specific areas of concern. For example, the supplier control subsystem is composed of 16 individual criteria. Specific areas of concern that may be identified include: the use of approved suppliers; periodic evaluations of suppliers; flowdown of applicable technical and quality requirements to suppliers; raw material verification; and others.

Through the use of detailed criteria and their relevant subsystems, quality management systems can be evaluated in a consistent manner. The data is collected and analyzed for trends annually. In FY 1995, the data was baselined so that the effectiveness of any industry actions to address issues previously reported can be detected and measured. Where appropriate, the analyses presented in this report were performed at both the criteria and the subsystem level.

Of the more than 1000 findings and observations recorded at the 477 facilities evaluated in FY 1997, only two identified significant safety concerns, i.e., findings for which immediate corrective action was required. The balance of the issues reported were not considered an immediate safety concern. The data collected did, however, indicate some very definite trends. Almost two-thirds of all of the issues were found within four subsystems: manufacturing processes, supplier control, tool and gauge, and design data control. In addition, the issues within these subsystems were concentrated in a few criteria. The subsystems and criteria where the most issues were reported are as follows:

Manufacturing Processes - Specific functions and operations necessary for the fabrication and inspection of parts and assemblies (e.g., machining, riveting, and assembling).

- Completed products/parts did not have proper identification markings.
- Work instructions did not adequately control the manufacturing process.
- Records were not generated or maintained for all significant provisions of the quality/inspection program which have an effect on control of FAA-approved design data, or if applicable, purchase order requirements.
- The evaluated facility operated outside the production limitations of the production certificate.

Supplier Control - The system by which the evaluated facility ensures supplier materials, parts, and services conform to FAA-approved design. For the purpose of this section, the term "supplier" includes distributors.

- Initial and periodic evaluations of suppliers were not made, as necessary, or corrective actions was not taken to correct system deficiencies.
- Receiving inspection failed to verify that supplier-furnished parts/services conformed to FAA-approved design data.
- Unapproved suppliers were used.
- The evaluated facility failed to flow down applicable technical and quality requirements to both U.S. and other country suppliers.
- Raw material, including process material (such as weld rod, etc.), was not verified or identified.

Tool and Gauge - The function which establishes control of precision measuring devices (e.g., tools, scales, gauges, fixtures, instruments, or automated measuring machines) used in fabrication, special processing, inspection, and test of detail parts, assemblies, and completed products to determine conformity to FAA-approved design.

- Tools and gauges were not initially approved or were not periodically inspected and calibrated.

Design Data Control - The planning and integration of the evaluated facility's procedures for continuously maintaining the integrity of design data, as approved by the FAA or FAA-delegated representatives, in the completed product. This includes software used in type-certificated aircraft or related products (airborne software).

- Changes to product design (including airborne software) were unapproved, undocumented, or uncontrolled.
- The facility lacked a drawing control system.
- Minor design changes were not approved under a method acceptable to the FAA. A TSO facility did not submit to the FAA all necessary revised data resulting from a minor change to the TSO article.

These four subsystems have been the most predominant areas for issues since the data was baselined in FY 1995. Additionally, the percentage of facilities with issues and the areas in which these issues predominantly occur has remained constant since FY 1995. A more detailed analysis of these trends is presented in *Section 3* of the report.

The FY 1995, FY 1996, and FY 1997 analyses have all indicated a direct correlation between systemic and isolated issues. All four of the subsystems mentioned above have the most systemic issues as well as the most isolated issues. Even at the criteria level, almost three-fourths of the top isolated issues are also the top systemic issues. One of the theories formulated to explain this apparent similarity between systemic and isolated issues is that given more investigation, sufficient evidence could have been uncovered to lead the evaluation team to determine the isolated issues to be symptoms of latent systemic breakdowns in the quality management system, thereby warranting them to be reclassified as systemic issues. This phenomenon will be studied further and reported on as results are obtained. A more detailed discussion of this subject is included in *Sections 3.3 and 3.6* of the report.

An analysis of the data collected to date indicates that systemic findings and systemic observations appear to occur with similar frequency (see *Section 3.2*). Systemic findings represent violations of the FAR and FAA-approved data or noncompliances by a supplier with the procurement document, whereas systemic observations represent violations of non-FAA approved data. Systemic breakdowns in a quality management system appear to occur based upon the functional area and do not appear to be affected by the type of data controlling those systems.

In addition to the various facility types having issues in similar areas, the data also indicates that, on average, the various facility types have them at an equivalent magnitude. In other words, all of the various facility types appear to be equal in the extent of issues and these issues appear to occur in similar areas. One area where differentiation does appear to universally exist is in system complexity, i.e., a small facility with simple systems will, on average, have a better compliance rate than a large facility with complex systems. *Sections 3.4 through 3.7* of this report provide more detail into the similarities and differences among various facilities.

The FY 1997 analysis builds upon the results of the FY 1996 analysis to provide significantly better insight into the influence internal audit programs have on compliance in areas other than internal audit. The data indicates that systemic issues within the critical area of internal audit can cause loss of quality management control within the areas that internal audit is attempting to monitor. Facilities which were found to be in noncompliance with their own internal audit procedures were twice as likely to have systemic issues in one or more of the other sixteen subsystems. Those facilities that violated their internal audit procedures had on average two more findings than those facilities following their internal audit policies and procedures. In fact, nearly every facility

that was not following its internal audit procedures had additional findings in other areas. Both industry and the FAA should carefully consider the implications of this trend. The analysis and its detailed findings are presented in *Section 3.7*.

Two notable events occurred during fiscal year 1997. The first was a direct result of an issue discovered during two separate ACSEP evaluations. There was the possibility that the National Institute of Standards and Technology (NIST) would not reissue radiographic calibration standards in time to avert the aviation industry's supply of the standards from exceeding their expiration dates. Once the FAA had notified NIST of the necessity of the standards, NIST accelerated its delivery schedule in time to avoid a shortage of the standards. The second event was the agreement between the FAA, Aerospace Industries Association (AIA), and the General Aviation Manufacturers Association (GAMA) to form a joint team to formulate hypotheses to explain the trends in the ACSEP data and to formulate corrective action plans. A discussion of these events can be found in *Section 3.10*.

Notice N8100.13, Aircraft Certification Systems Evaluation Program Criteria for Delegated Facilities, was issued on July 24, 1997. This notice formally incorporated the evaluations of Delegation Option Authorization (DOA), Designated Alteration Station (DAS), and Special Federal Aviation Regulation No. 36 to FAR part 121 (SFAR-36) facilities into ACSEP. Analysis of the results from these facilities has not been included in this report since program implementation occurred late in the fiscal year.

For the fourth year in a row, the continuous improvement initiatives implemented in ACSEP have resulted in a reduction in difficulties encountered during ACSEP evaluations. Evaluation teams reported 89 percent fewer problems in complying with the ACSEP order and performing evaluations. In addition, there has been a simultaneous increase in customer satisfaction with ACSEP evaluations. As part of the ACSEP continuous improvement process, the facility's management is provided with a feedback summary on which to record their assessment of the conduct of the evaluation team. All phases of an ACSEP evaluation are addressed from pre-evaluation notification through post-evaluation review of any findings and/or observations. Less than one percent of the facilities returning a feedback summary in FY 1997 reported dissatisfaction with the conduct of the ACSEP evaluation teams. See *Section 4* for additional information on the continuous improvement program of ACSEP.

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FY 1997 Report

1. Introduction

This report summarizes the results of the Aircraft Certification Systems Evaluation Program (ACSEP) and provides a comprehensive view of the program's results from October 1996 through September 1997. The analysis of the data provides insight into procedural compliance trends within the aviation industry and highlights some specific areas of concern.

Order 8100.7, Aircraft Certification Systems Evaluation Program, was released in its final form in March 1994. Prior to this, a draft version was used to perform the evaluations and to collect data. The final order contained some significant changes in the categorization and interpretation of the individual criteria and the method of recording evaluation results. Therefore, data collected for FY 1994 and earlier is not comparable to the data collected after the revised order was published except in a very general nature.

The FY 1995 ACSEP report is considered the baseline from which all time-related trend analysis is established. With the collection of three years of comparable data, this report is the first to present preliminary trend analysis. It should be noted that due to the short timeframe for which data is available, the trends presented in this report are only preliminary. More comprehensive trend analysis will be presented in future reports as the collection of data to permit reliable analysis is accomplished.

1.1 Report Structure

The report is presented in four sections with *Section 1* providing an introduction and overview of the program status. *Section 2* provides summary conclusions for the data collected in FY 1997. *Section 3* provides a consolidation of the analyses that led to the conclusions presented in *Section 2*. *Section 4* provides the results of the ACSEP improvement effort including feedback from industry, lessons learned, and comments received regarding the ACSEP evaluations. Additionally, there are five appendices providing: a brief history and background of ACSEP; a list of definitions; detailed data regarding the specific findings and observations; a summary of a detailed regression analysis of predictive trend factors based on facility complexity; and an explanation of some of the analysis methods.

1.2 Program Overview of ACSEP

This subsection provides an overview of the ACSEP program and a brief history of its growth. The ACSEP was developed as a result of numerous years of experience with Quality Assurance Systems Analysis Review (QASAR) audits and observations made during an interim audit program called "Operation SNAPSHOT." The most significant differences between QASAR and ACSEP are:

a) ACSEP evaluations are performed in accordance with consistent and standardized evaluation criteria.

b) The evaluation criteria used during an ACSEP evaluation was developed with extensive input and cooperation from the aviation industry to ensure that emerging technologies are addressed.

c) ACSEP evaluation results are maintained in a centralized database that allows statistical trend analysis.

d) An annual report of the aggregate ACSEP evaluation results is published.

e) ACSEP actively incorporates the evaluation of priority parts suppliers to the production approval holders. Facilities with engineering delegations are also evaluated. The facilities that are evaluated by ACSEP are:

- Approved Production Inspection System (APIS)
- Production Certificate (PC) and Production Certificate Extension (PCEX)
- Parts Manufacturer Approval (PMA)
- Technical Standard Order (TSO) authorization
- Priority Part Suppliers (PPS) to the above production approval holders
- Delegation Option Authorization (DOA)
- Designated Alteration Station (DAS)
- Special Federal Aviation Regulation No. 36 to FAR part 121 (SFAR-36)

A more detailed history and background of ACSEP, the structure of the evaluation teams, and departmental interactions are discussed in *Appendix A*.

Note: Notice N8100.13, Aircraft Certification Systems Evaluation Program Criteria for Delegated Facilities, was issued on July 24, 1997. This notice formally incorporated the evaluations of DOA, DAS, and SFAR-36 facilities into ACSEP. Analysis of the results from these facilities has not been included in this report since program implementation occurred late in the fiscal year.

The transition from QASAR to ACSEP occurred in FY 1993. Since then, the number of evaluations performed each year has increased an average of 24 percent annually. *Figure 1-1* shows the growth of the program from FY 1993 to the projected number of evaluations scheduled for FY 1998. The growth in the program was facilitated by an increase in the number of qualified manufacturing, engineering, and flight test personnel fully trained to perform ACSEP evaluations. The relatively rapid growth in the number of evaluations performed at facilities outside of the U.S. — from zero international evaluations in FY 1993 to 54 evaluations planned in FY 1998 — is indicative of the increasing globalization of aviation supplier relationships.

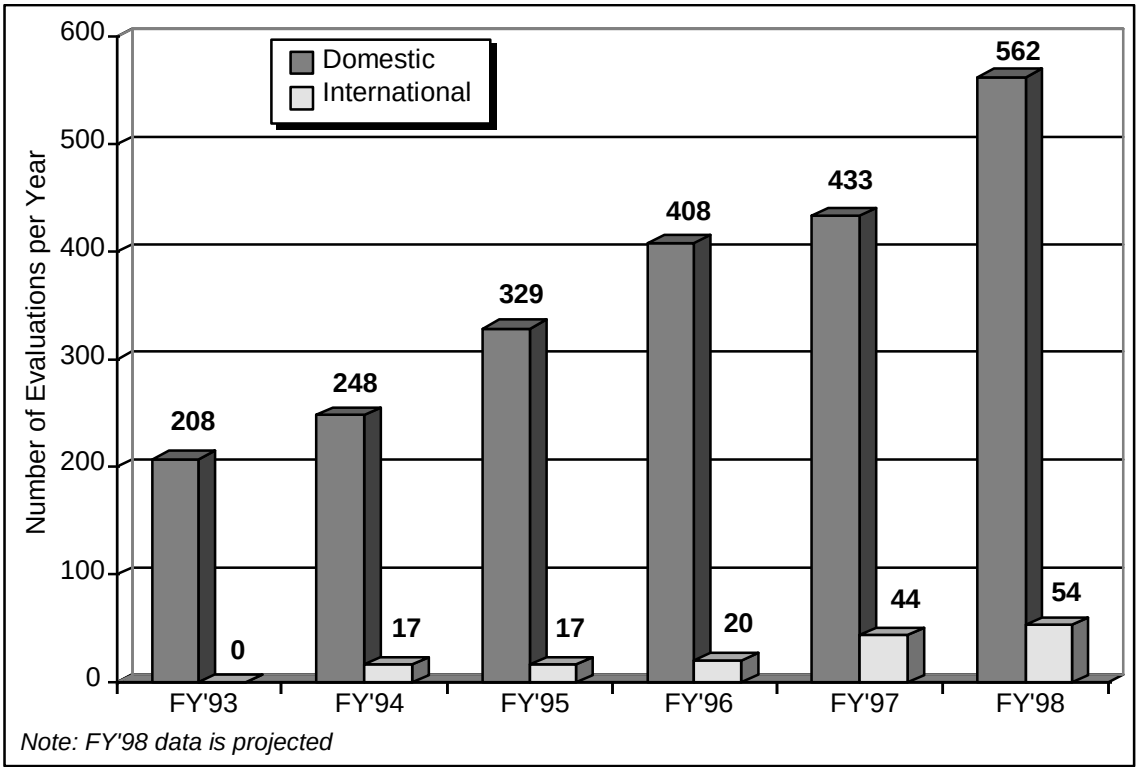

Figure 1-1.—Growth in annual ACSEP evaluations.

The number of facilities holding FAA production approvals has steadily increased since FY 1993 at a rate of six percent per annum. *Table 1-1* itemizes the population of various production approval holders[1]. The growth in the number of evaluations among the various facility types is presented in *figure 1-2.*

TABLE 1-1.— The population[2] of PAHs for fiscal years 1993 through 1997

Fiscal Year	Parts Manufacturer Approval (PMA)	Technical Standard Order (TSO) Authorization	Production[3] Certificate (PC)	Approved Production Inspection Systems (APIS)	Total number of Production Approval Holders (PAH)
1993	1,087	367	73	13	1,540
1994	1,140	379	74	14	1,607
1995	1,106	309	88	5	1,508
1996	1,413	342	70	13	1,838
1997	1,437	364	98	8	1,907

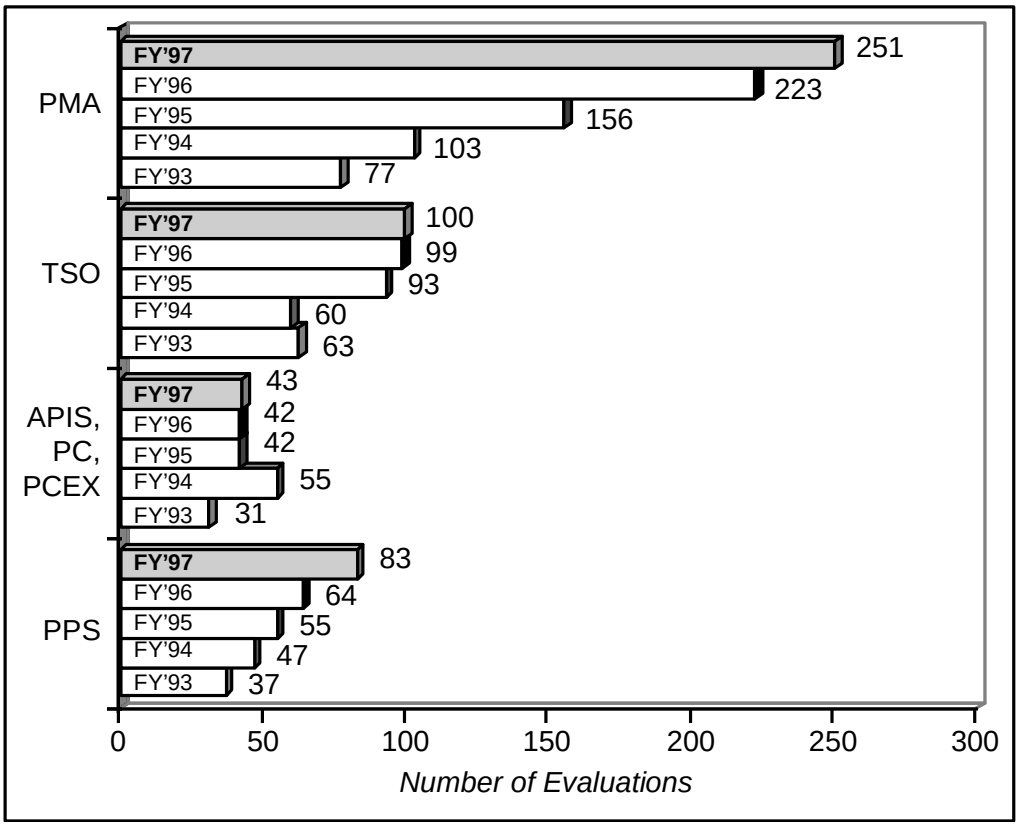

Figure 1-2.—Distribution of ACSEP evaluations by facility type - domestic and international.

[1] Facilities with multiple production approvals are accounted for only once in accordance with the following order of precedence: PC (or PCEX), TSOA, APIS, and PMA.

[2] This table is a compilation of data received from the individual directorates and is included in this report for reference only.

[3] Includes PC extensions

ACSEP evaluations were conducted by the Aircraft Certification Service's four directorates. There were 17 nationally led evaluations headed by a team leader from AIR-200. *Figure 1-3* shows the distribution of all evaluations among the four directorates.

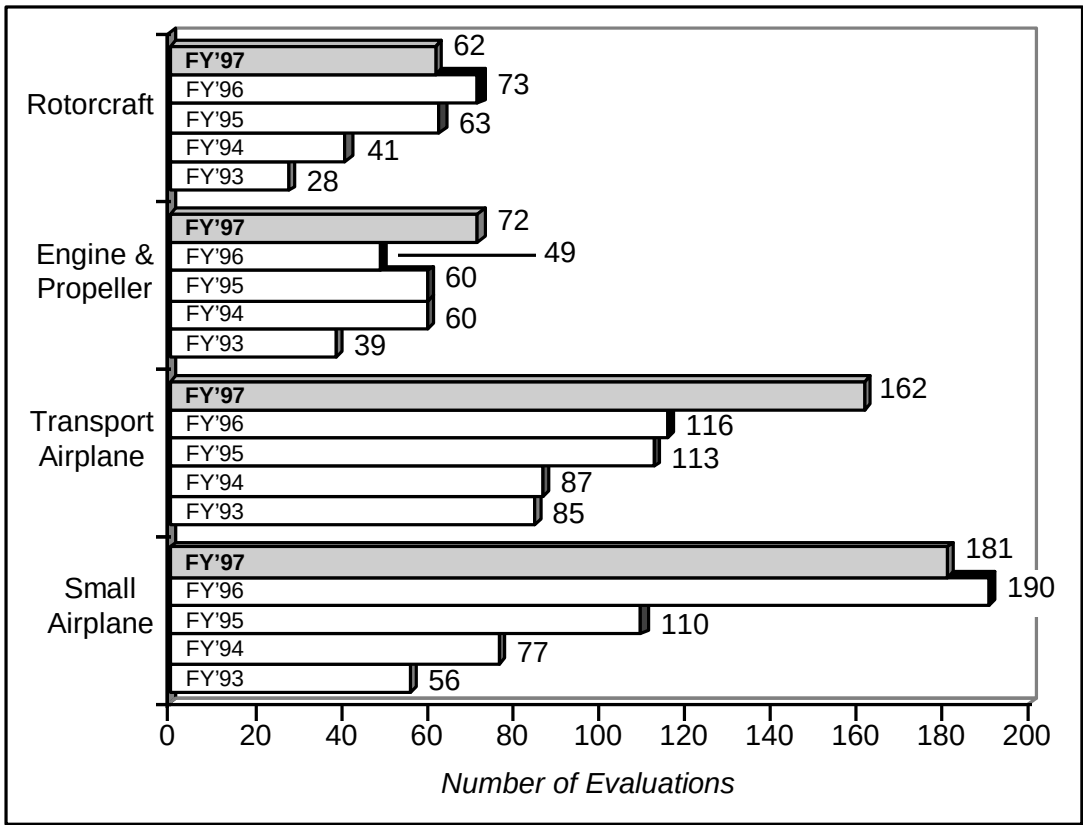

Figure 1-3.—Distribution of ACSEP evaluations by directorate - domestic and international.

1.3 The Data Collected During an ACSEP Evaluation

The ACSEP was designed to determine if FAA production approval holders, their priority parts suppliers, and delegated facilities are complying with the requirements of applicable Federal Aviation Regulations (FAR) and the procedures established to meet those requirements. It also surveys the application of standardized industry practices not required by the FAR or FAA-approved data to identify national trends that may require development of new or revised regulations, policy, or guidance. The elements of the evaluation are referred to as criteria. Data is collected on noncompliance and applicability with respect to those criteria.

During an ACSEP evaluation, the actual operating practices of a facility are compared to the FAR, FAA-approved data, and the facility's internal procedures. Any inconsistency

discovered (termed issue in this report) is classified and recorded. An issue is classified by its type and the subsystem under which it is noted. There are five issue types:

Safety Finding - an issue that compromises immediate continued operational safety.

Systemic Finding - an issue that is systemic in nature, i.e., is pervasive, repeatable, or represents a breakdown in the quality management system. For an issue to be categorized a finding, it must also be a noncompliance to a FAR or FAA-approved data (or noncompliances with the procurement instrument when a facility is a supplier).

Systemic Observation - an issue that is systemic in nature and is a noncompliance to facility procedures that are not FAA approved.

Isolated Observation - an issue that is of an isolated or nonsystemic nature, i.e., isolated to a particular person and/or timeframe and does not represent a breakdown in the quality management system. For an issue to be categorized an isolated observation, it must also be an isolated noncompliance to a FAR or FAA-approved data (or a noncompliance with the procurement instrument when a facility is a supplier).

FAR-Based Observation - the discovery of FAA-approved data that is inconsistent with the FAR.

The second form of classification of an issue is the subsystem under which it is discovered. In total, there are 17 subsystems that represent a quality management system:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAR Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

Each subsystem is further divided into “criteria.” The criteria were developed with extensive assistance from industry in order to fully represent the detailed areas within each of the 17 subsystems. A process also exists to identify potential new criteria should the existing criteria not address a particular functional area within a subsystem. The subclassification of issues into the detailed criteria allows the FAA to identify specific areas of concern and allows industry to focus corrective action on these specific areas of concern. For example, the supplier control subsystem is composed of 16 individual criteria. Specific areas of concern that may be identified include: the use of approved suppliers; periodic evaluations of suppliers; flowdown of applicable technical and quality requirements to suppliers; raw material verification; and others.

2. Conclusions of Data Analysis

Analysis of the FY 1997 ACSEP evaluation data supports the following conclusions[4]:

- There is little difference in the distribution of systemic findings and systemic observations either at the subsystem or criteria levels (see *Section 3.2 and 3.6*). Both issue types are common in that both record systemic issues. They differ in that a systemic finding records a noncompliance with the FAR, FAA-approved data, or a noncompliance by a supplier with the procurement instrument, whereas a systemic observation records a noncompliance with a procedure that is neither FAR based nor approved by the FAA. The frequency at which issues are recorded within the subsystems or criteria is the same for the two types of issues. The FY 1995 and FY 1996 data and reports also supported this conclusion. From a data analysis standpoint, findings and systemic observations can be considered as one classification of issues that can be combined when analyzing compliance distributions and trends.

- The various facility types have issues in the same areas. The distribution of issues among the various subsystems and criteria are statistically similar for all of the facility types (see *Sections 3.5 and 3.6*). This similarity among the facility types was also noted in the FY 1995 and FY 1996 reports.

- All of the facility types appear to have similar compliance rates, i.e., the ratio of facilities with issues to those without issues. With little exception, no one facility type appears to have a significantly higher or lower rate of compliance with its established policies and procedures than any other facility type (See *Section 3.4*). Similar rates were seen in the FY 1995 and FY 1996 data as well. There appear to be only three instances of significant variances in compliance rate among facilities:
  - PC holders had a higher proportion of facilities with systemic issues in FAA reporting requirements.
  - PC holders had a higher proportion of facilities with systemic tool & gauge issues.
  - PC holders had a higher proportion of facilities with systemic issues in inspection methods and plans.

  Sections 3.5 and 3.6 provide additional details of these variances.

- The majority of findings and observations are concentrated within a few subsystems: manufacturing processes, supplier control, tool and gauge, design data control, nonconforming material, and material handling/storage (see *Section 3.5*). The issues are also concentrated within a few individual criteria (see *Section 3.6*). In fact, only

[4] Due to the low number of international evaluations and correspondingly large prediction error of such a small sample, the conclusions in this report — **unless specifically stated otherwise — are based on the results of domestic facilities only.**

slightly more than one-half of the criteria had systemic findings and observations recorded against them. The concentration of issues into a select few areas has remained relatively consistent since being first reported in FY 1995.

- Systemic issues and isolated issues are similarly distributed among the subsystems and criteria. Those subsystems and criteria where the most systemic issues were recorded also were the subsystems and criteria where the most isolated observations were recorded. This is consistent with both FY 1995 and FY 1996 data. The cause of this correlation, however, is unclear. *Section 3.3* provides additional detail on this phenomenon.

- More complex quality management systems have a higher probability of having systemic issues than simple systems (i.e., the larger the facility, the more parts and products produced, the more processes in place, and the more complex the facility's controls, the higher the probability of there being issues with those systems). The FY 1995 and FY 1996 analyses also provided strong evidence of the direct relationship between quality management system complexity and the presence of systemic issues. See *Section 3.4 and Appendix D* for additional information on the relationship between facility complexity and the occurrence of issues.

- International and domestic facilities appear to have similar issues (see *Section 3.9*). The small sample size of international facilities, however, precludes any further assessment of the international facilities.

- Analysis aimed at uncovering indicators of compliance rates highlighted a very significant area of opportunity. Facilities with discrepant internal audit programs invariably had systemic issues in other areas. The noncompliance rate for those facilities with discrepant internal audit programs was twice that of the rest of the industry. Section 3.8 provides a summary of this analyses.

A summary of the analyses that support all of these conclusions is presented in *Section 3*.

3. Data Analysis

3.1 Safety Related Findings

Of the more than 1000 findings and observations recorded in FY 1997, only two identified immediate safety concerns. These safety findings were for a violation of material handling and storage procedures for the inspection of age controlled products (criteria 12Q5), and for a violation of manufacturing process procedures to ensure that parts will be inspected for conformity with FAA-approved design data (criteria 4Q1). Due to the relatively rare occurrence of safety findings, future safety findings will continue to be monitored and compared to past safety findings prior to the formulation of any conclusions.

3.2 Systemic Issues (Findings vs. Systemic Observations)

Analysis has demonstrated that systemic findings and systemic observations are statistically equivalent to each other (see *figures 3-1 through 3-3*). They are also, in fact, both similar in definition. They differ in that a systemic finding records a noncompliance with the FAR, FAA-approved data, or a noncompliance by a supplier with the procurement instrument, whereas a systemic observation records a noncompliance with a procedure that is neither FAR based nor approved by the FAA. Aside from this difference in definition, they are both systemic in nature and are both non-observances to established processes or procedures. Analysis supports the assertion that the frequency at which issues are recorded within the subsystems is the same for the two types of issues. The previous reports also showed a similarity in the occurrence of findings and systemic observations. Analysis of the systemic issues relevant to the various facility types and preliminary trends over the last three years are presented later in this report.

Due to the strong relationship between these two types of systemic issues, findings and systemic observations can be considered as one classification of issues that can be combined when analyzing compliance distributions and trends. This report often presents the analysis of systemic issues combined rather than separately as findings and observations. The combining, or pooling, of these two sets of data for further analysis almost triples the reliability of the analysis results due to the reduced error of larger sample sizes. Unless otherwise specified, all future references to systemic issues will relate to occurrences of both findings and systemic observations. Additionally, unless specified, it can be presumed that all analysis was performed with pooled finding and systemic observation data.

Note: The following charts present three important features of the evaluation data: the proportion of facilities evaluated in FY 1997 that had findings and/or observations, the distribution of those findings and/or observations within the subsystems, and a statistical probability that those facilities not evaluated in FY 1997 would have similar issues. For example, *figure 3-1*, Manufacturing Process, should be interpreted as 22 percent of the facilities evaluated had findings issued in FY 1997 for manufacturing processes; those manufacturing process findings make up 27 percent of all of the findings issued; and should repeated random samples of all facilities be made, the results would be within four percent of those evaluated in 95 percent of the random samples. The charts serve a dual purpose: (1) to illustrate the actual results of FY 1997 evaluations and (2) to predict the results that might occur at facilities not evaluated.

For the purpose of making predictions, the prediction error is a measure of the precision of those predictions based on the available data. *Appendix E* contains a detailed explanation of the equations and assumptions used in calculating prediction error.

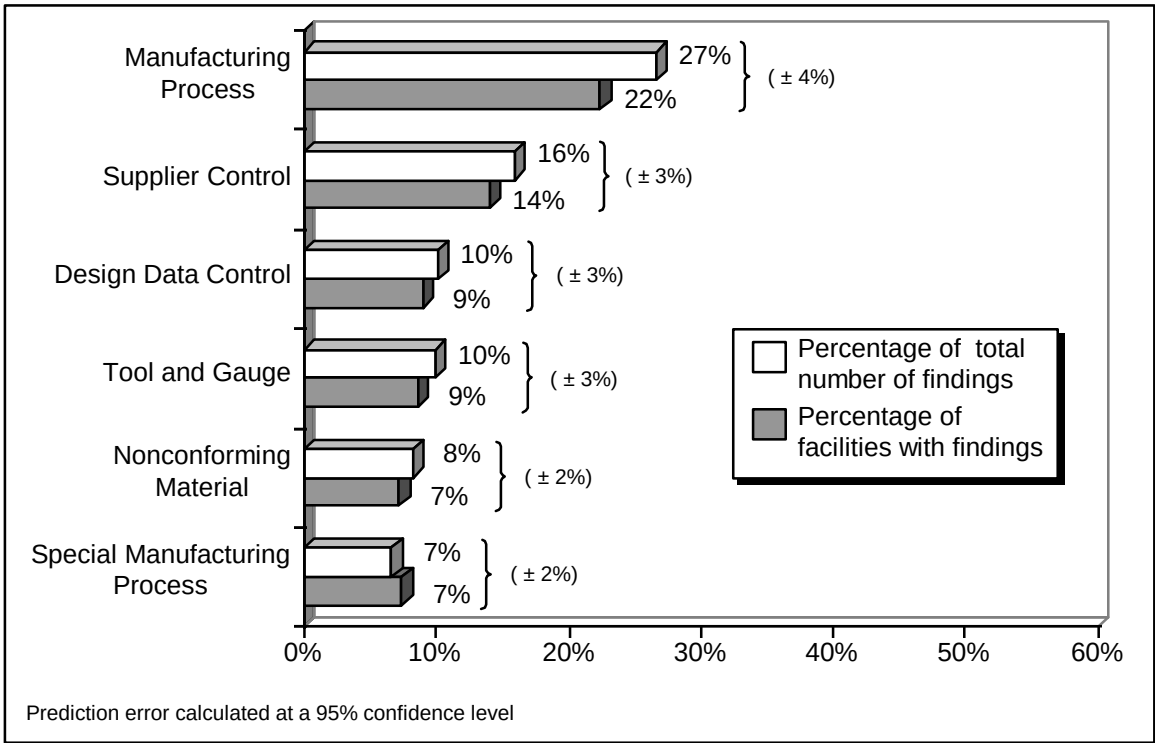

Figure 3-1.—Systemic findings – all facility types[5].

[5] Most of the charts presented in this report are plotted with a greater precision than the data labels used to annotate them. Apparent differences between data points equally labeled are due solely to rounding the data label values.

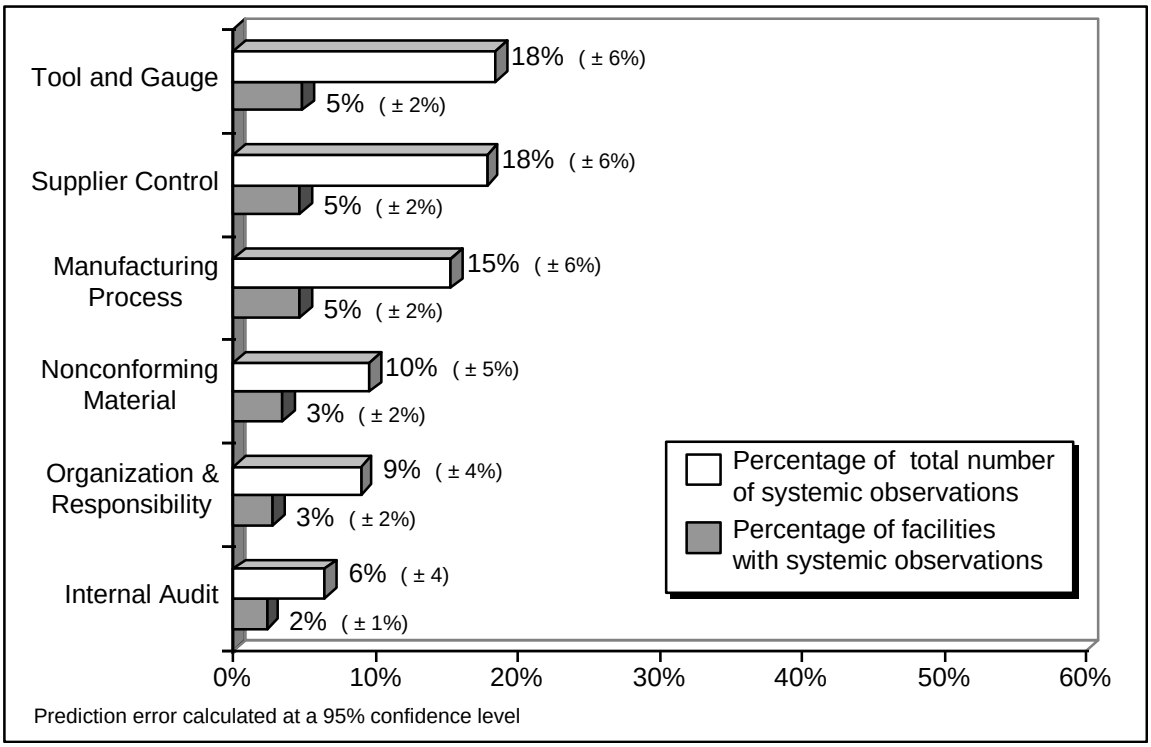

Figure 3-2.—Systemic observations – all facility types.

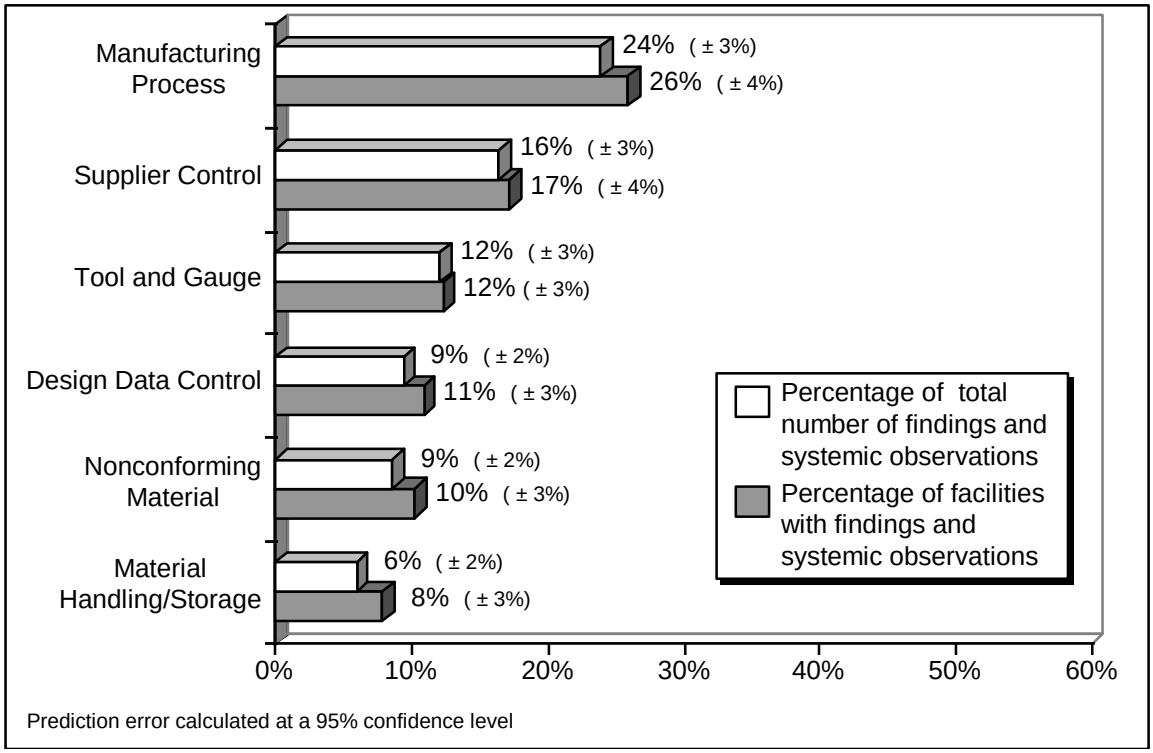

Figure 3-3.—Systemic findings and systemic observations – all facility types.

3.3 Isolated and Systemic Issues

There appears to be similarity between the distribution of systemic issues and the distribution of isolated issues. The difference between the two types of issues is:

Systemic issue	• System breakdown • Pervasive • Repeatable • Safety related
Isolated issue	• Not a system breakdown • Confined • Random event

Figure 3-4 represents the frequency distribution of isolated observations at the subsystem level. Notwithstanding the reduced rate of occurrence of isolated observations, the frequency distribution of these observations is similar to the distribution of systemic issues (refer to *figure 3-3*). *Table 3-1* compares the top ten percentile of isolated observations at the criteria level to those criteria with systemic issues also within the top ten percentile. Almost two-thirds of the top isolated issues are also the top ten percentile systemic issues. The correlation between isolated and systemic issues has been seen for the last three years. This apparent similarity between the frequency distributions at both the subsystem and criteria level supports the conclusion that they are somehow related.

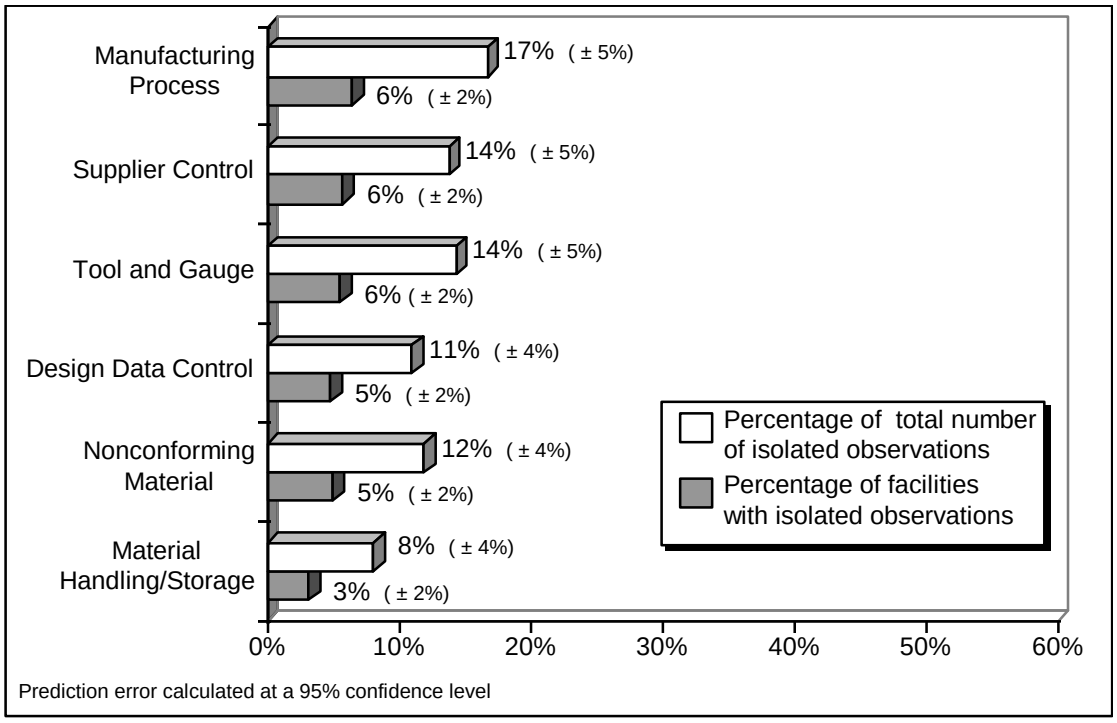

Figure 3-4.—Frequency distribution of isolated observations – all facility types.

TABLE 3-1. —Top ten percentile of isolated issues compared to the top ten percentile of systemic issues

Criteria	Description	Rank of Isolated Observation	Systemic Issues
10Q1	Initial & periodic evaluations of suppliers	1	✗
11Q2	Permanent identification of scrap material	2	✗
12Q5	Identification of age control parts	3	
11Q1	Control of nonconforming products	4	✗
15M1	Internal audit program	5	✗
2E1	Design change approval	6	
7Q1	Approval/inspection of tools and gauges	7	
4P4	Work instructions control manufacturing processes	8	✗
✗ = within top ten percentile of systemic issues			

Assuming the correlation exists, and there is strong evidence from the FY 1995, FY 1996, and the FY 1997 data to suggest that it does, there are two probable causes for this apparent similarity between systemic and isolated issues. One theory is that the distribution of isolated issues follows the natural probability frequency of systemic issues, i.e., those areas that are more prone to systemic issues are also more likely to have isolated issues. Another theory is that a large portion of the isolated issues are indications of larger systemic issues rather than solely isolated issues. In other words, given more investigation, sufficient evidence could have been uncovered to lead the evaluation team to determine the issues to be symptoms of latent systemic breakdowns in the quality management system, thereby warranting them to be reclassified as findings. The occurrence of this phenomenon over the last three years warrants further study into the cause of this apparent correlation between isolated and systemic issues.

Due to the relatively rare occurrence of FAR-based observations, i.e., only 40 recorded in FY 1997, no reliable comparison can be made with the other types of issues.

3.4 Comparison of Facility Types

This section compares the occurrence of issues among the various facility types. However, we need to first consider any effect facility size and complexity may have on the results of this analysis. The next subsection discusses the effect that facility complexity has on the ACSEP evaluation results for individual facility types. The subsequent subsections discuss the particular results for each of the three types of issues: systemic, isolated, and FAR-based.

3.4.1 Complexity of Systems

Both the number of systemic and isolated issues and the probability of a facility having such issues correlate very strongly to the complexity of the systems in use at the facilities being evaluated. The probability of a facility having processes noncompliant with established policies or procedures appears to increase proportionately with system complexity (see *Figure 3-5*). It should be noted, however, that a facility's complexity (or simplicity) does not guarantee the presence or absence of noncompliances. There were several examples of fully compliant large, complex systems, and conversely, several examples of small, simple systems with several noncompliances. Regression analysis techniques[6] indicate a common factor that can be used to predict this phenomenon. This factor was used to normalize the data for comparisons among the various facilities[7]. This normalization removes the apparent bias produced when comparing, for example, a very large, high-technology PC holder with a small, low-technology supplier. The specific results of the normalized comparisons among the various facility types are discussed in further detail in the following subsections.

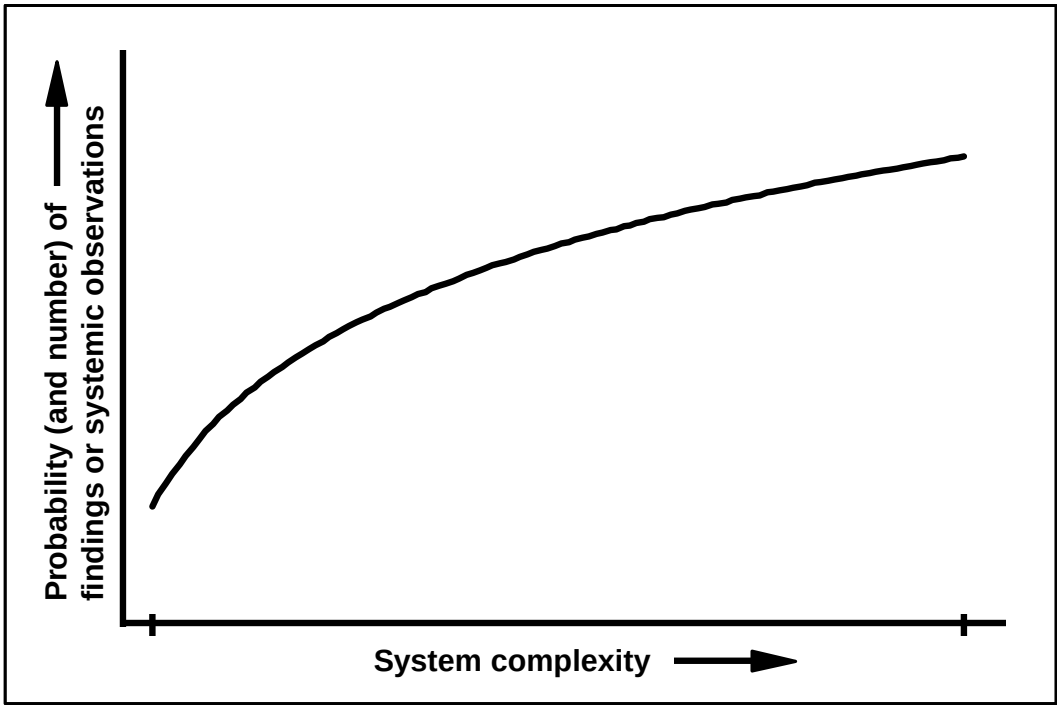

Figure 3-5.—Systemic issues and system complexity are related.

[6] See *Appendix D* for the details of the regression analysis.

[7] APIS holders were not included in the normalized analysis because of the large prediction error caused by the small number of data points.

3.4.2 Systemic Issues

The FY 1997 data indicates that the occurrence of systemic issues was relatively similar among the various facility types with the exception of TSO authorizations having a slightly higher probability of systemic issues. Due to the relatively small number of data points associated with using only one fiscal year's data, the error rate is unacceptably high and would tend to mask subtle differences between the facility types. Pooling the FY 1996 and FY 1997 data[8] yields an overall higher reliability than either of the fiscal year's data alone. The coefficient of dependencies, R^2, for the individual facility types were typically over 75 percent, indicating a reasonably strong goodness of fit between the trend lines and the actual data. The pooled FY 1996 and FY 1997 data indicates that PC holders, PMA holders, and priority parts suppliers had a statistically similar percentage of facilities with systemic issues. However, TSO authorization holders had a significantly higher percentage of systemic issues than either PMA holders or priority parts suppliers and marginally higher than PC holders. *Figure 3-6* presents the pooled data presented normalized for complexity.

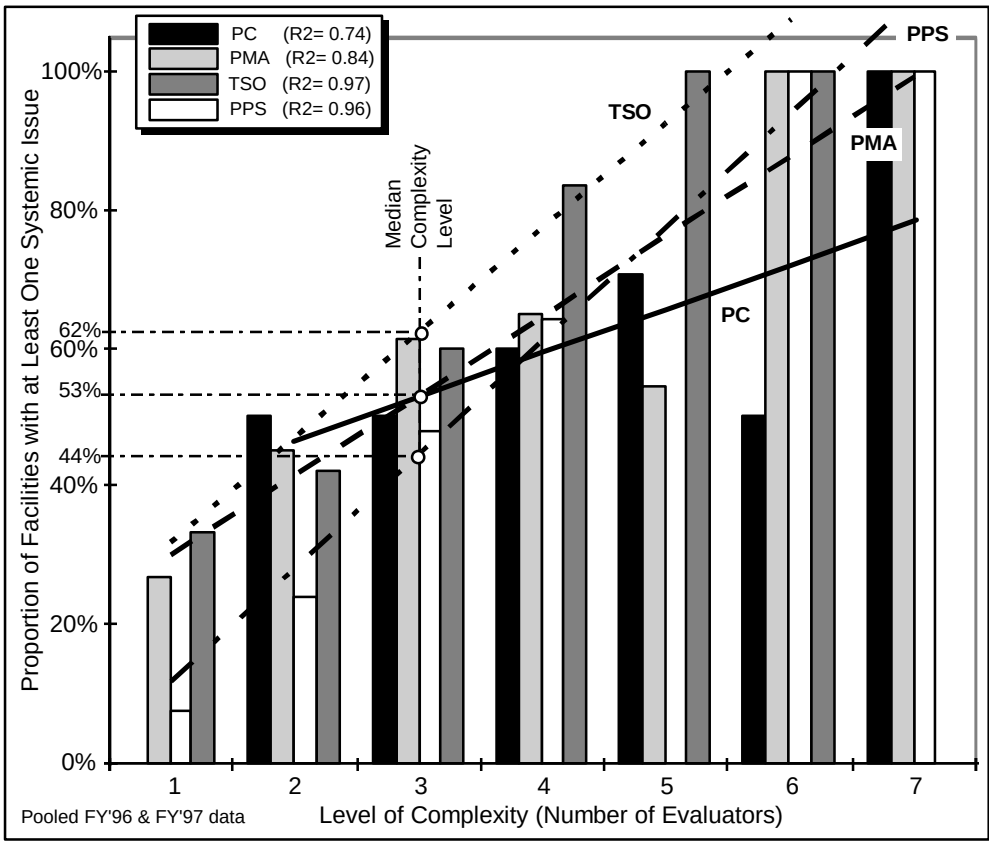

Figure 3-6.—Comparison between the facility types – adjusted for complexity.

[8] See *Appendix E* for the justification for pooling the data.

Figure 3-7 presents the same data, but with error bars to highlight the variance in the data[9]. For ease of comparison, the median facility complexity of three evaluators per facility was used.

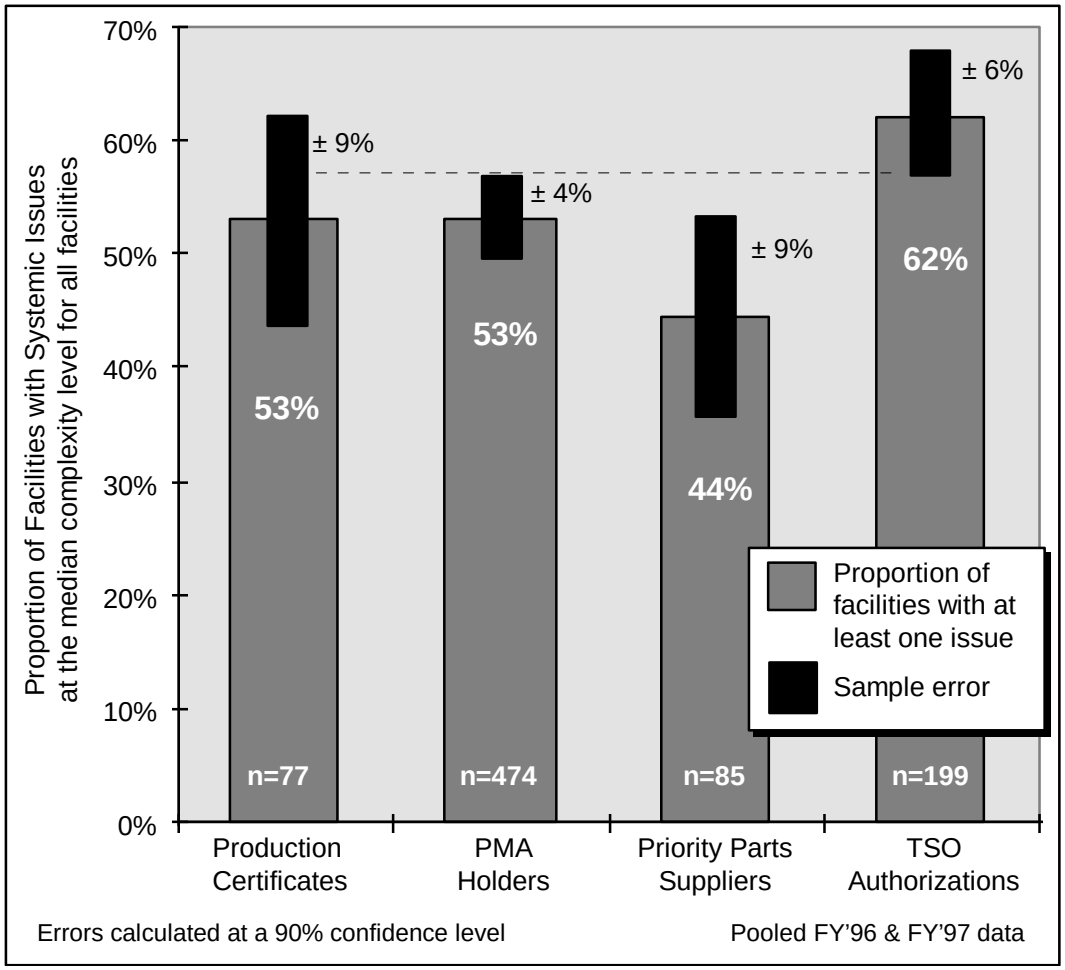

Figure 3-7.—Comparison of the percentages of facilities with at least one systemic issue.

The data presented in *figures 3-6 and 3-7* is consistent with the same data presented in the FY 1996 report. The one exception to this last statement is a significant drop in the percentage of priority parts suppliers with systemic issues (the FY 1996 analysis indicated 67 percent of priority parts suppliers had systemic issues[10] at the same median complexity level).

[9] See *Appendix E* for an explanation of the use of a 90% confidence interval.

[10] The FY 1996 report indicated that 64 percent of priority part suppliers had systemic issues at the mean complexity level of 2.8. Due to some outlying data collected in FY 1997, the more appropriate median complexity level of 3.0 is used for the FY 1997 report. Therefore, in order to make a proper comparison between the two years, the FY 1996 data was analyzed using the median complexity level of 3.0, generating a 67 percent result.

A comparison of the normalized data was also made between the individual FY 1995, FY 1996, and FY 1997 data in order to identify potential trends and to validate the assumption that pooling FY 1996 and FY 1997 data is appropriate. There was little change in the percentage of PMA holders and TSO authorizations with issues from FY 1995 to FY 1997. Therefore, the FY 1996 and FY1997 data for these two facility types is considered to be from a stable population and appropriate for pooling.

PC holders with systemic issues dropped significantly from FY 1995 to FY 1996 and subsequently rose in FY 1997. *Figure 3-8* illustrates the fluctuation in the proportion of PC holders with systemic issues over the three years. The FY 1996 report introduced the theory that the drop in the proportion of PC holders with issues was caused by facility selection bias introduced in the initial scheduling of ACSEP evaluations. This scheduling bias theory is strongly supported by the subsequent increase in PC holders with systemic

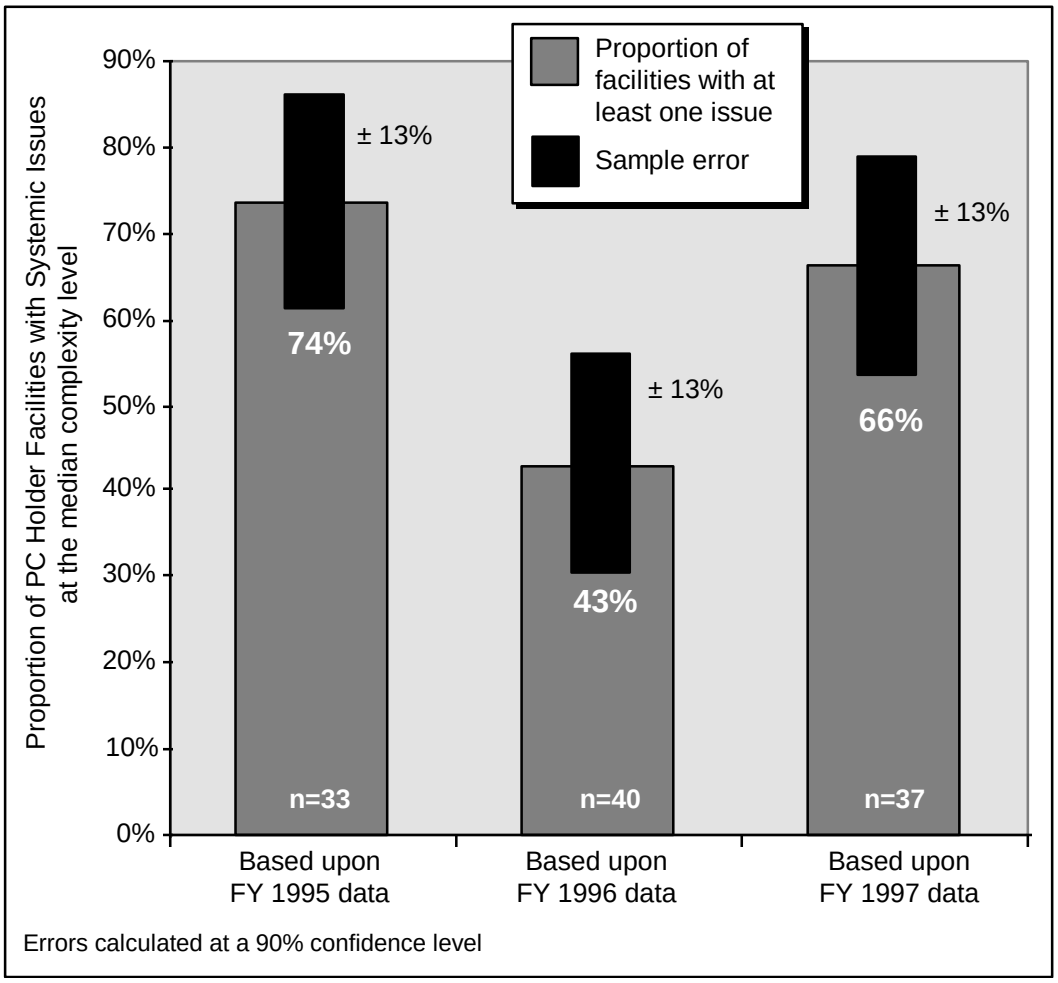

Figure 3-8.—Cyclical change in the percentage of PC holders with systemic issues from FY 1995 to FY 1997.

issues during FY 1997. The pooling of two consecutive years of PC holder data is not only considered appropriate under these circumstances, it is a means of compensating for a biannual cyclical variation in the data.

The three year analysis also suggests the possibility of a downward trend in the percentage of priority parts suppliers with systemic issues. *Figure 3-9* displays the apparent downward tendency in the probability of systemic issues at priority parts suppliers. However, the data for any two consecutive years is within statistical tolerances and can be considered similar. The data from FY 1996 and FY 1997 is considered to be from a relatively stable population and suitable for pooling. Additional discussion on possible trends of the last three years of data is provided in *Chapter 3.7*.

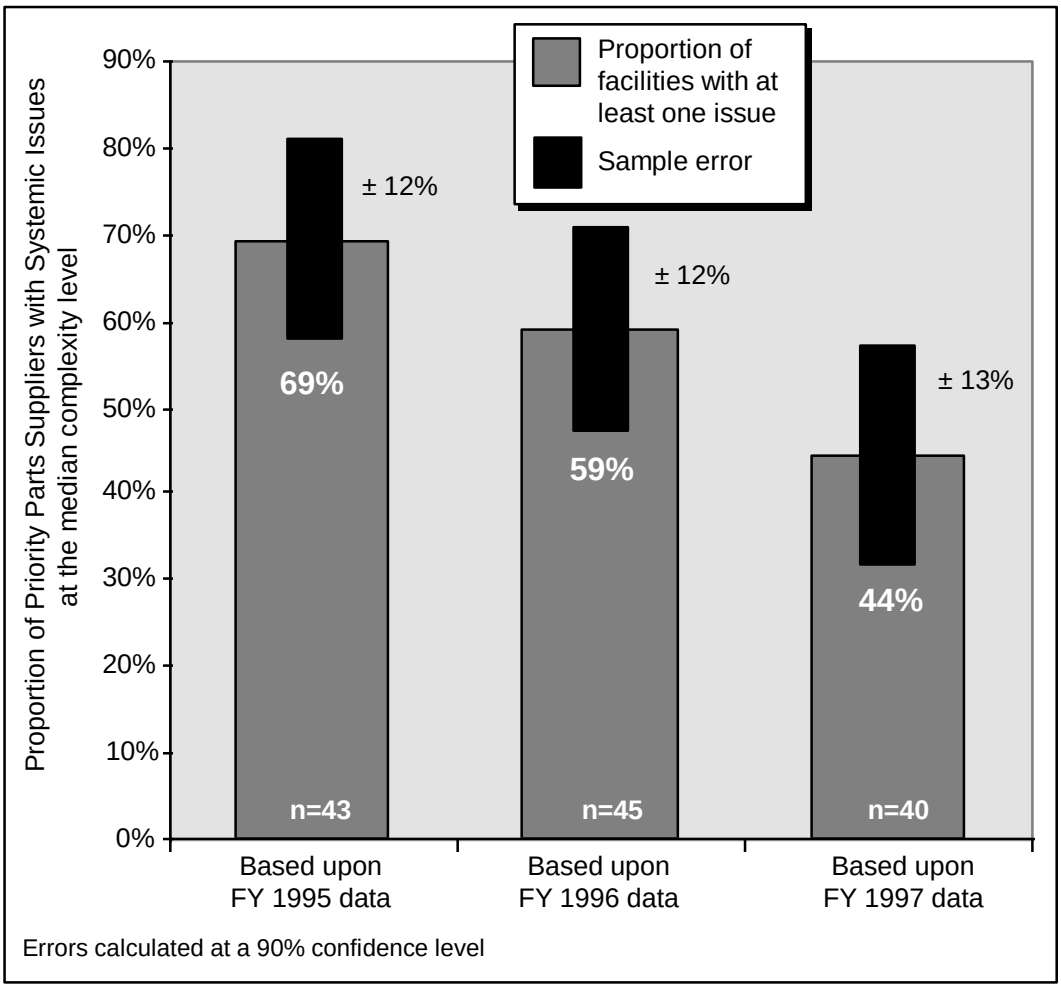

Figure 3-9.—Reduction in percentage of priority parts suppliers with systemic issues from FY 1995 to FY 1997.

3.4.3 Isolated Observations

The same type of analysis as presented in the previous subsection was also performed on the isolated observations. The analysis of FY 1997 data indicates that isolated observations are relatively equivalent among the different facilities, except that relatively fewer PMA facilities had isolated observations than the rest of the facility types. There is, however, a relatively high sample error associated with the analysis of any one fiscal year's data. Pooling two years of data drops the error rate into an acceptable range. The analysis of FY 1996 and FY 1997 pooled data indicates that all facility types are similar within statistical limits. Notwithstanding, PC and PMA holders appear to have marginally fewer isolated observations than priority parts suppliers and TSO authorizations. For clarity, only the analysis of the pooled data at the median complexity level of three evaluators per facility is shown in *figure 3-10*.

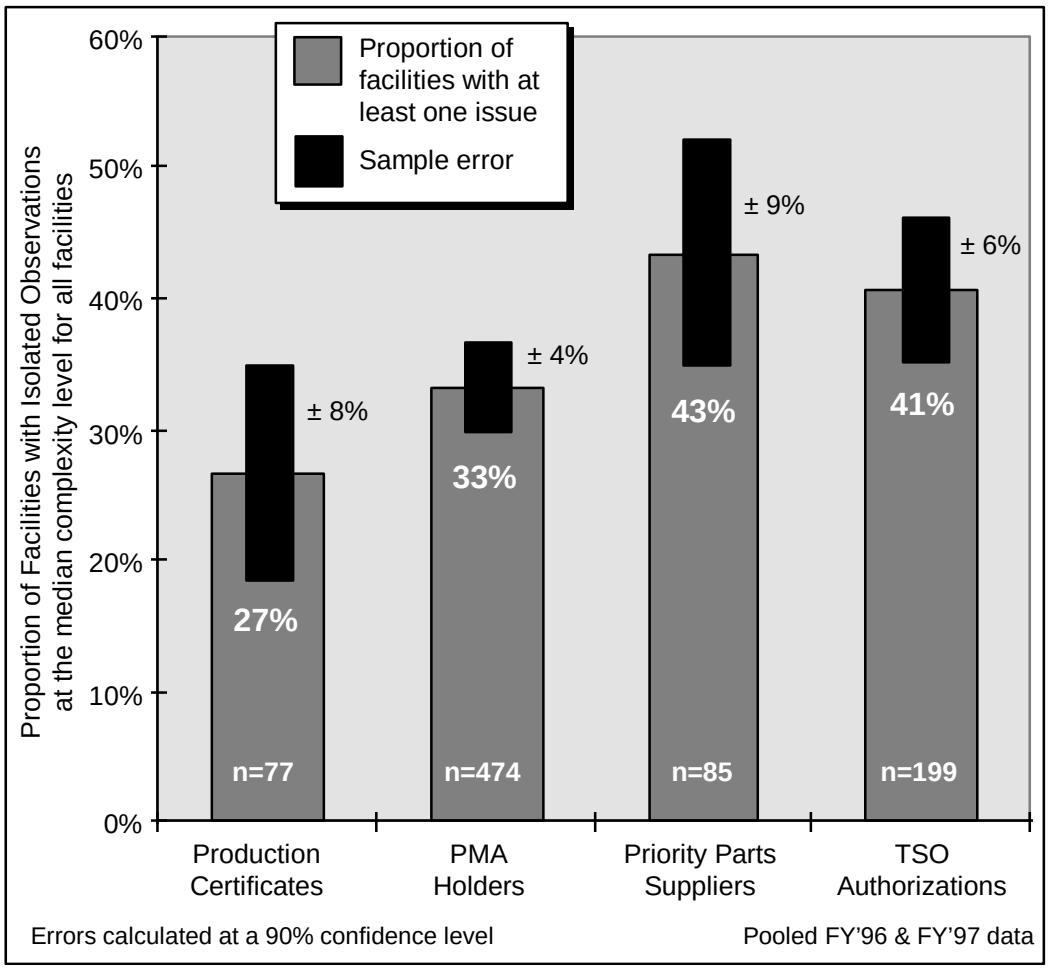

Figure 3-10.—Comparison of isolated observation rate for the various facility types.

3.4.4 FAR-based Observations

The probability of FAR-based observations for FY 1997 was relatively similar between PC holders and TSO authorizations. PMA holders had a significantly lower probability of FAR-based observations than the other two facility types. The pooled FY 1996 and FY 1997 data indicated that PMA holders had a lower probability of FAR-based observations than TSO authorizations. PC holders and PMA holders had similar probabilities as did PC holders and TSO authorizations. For clarity, only the pooled analysis at the median complexity level of three evaluators per facility is shown in *figure 3-11*.

As indicated in the FY 1996 report, the FY 1996 data indicates that 90 percent of all FAR-based observations were for TSO authorization and PMA facilities, 40 percent and 50 percent respectively. The FY 1997 data indicates that FAR-based observations are fairly evenly distributed among the three facility types. There were far too few FAR-based observations to make any firm conclusive statements concerning this cyclical fluctuation in results.

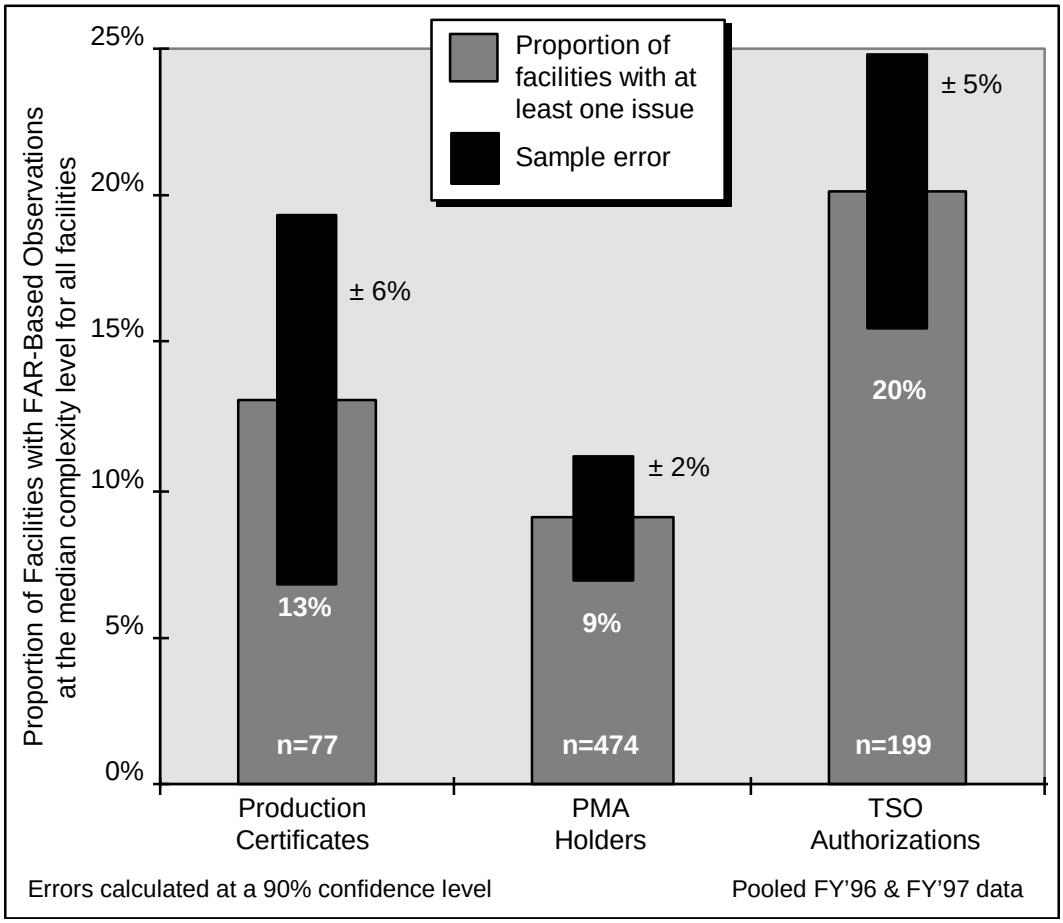

Figure 3-11.—Comparison of FAR-based observation rate for the various facility types.

3.5 Subsystem Issues

3.5.1 Similarity Among Facility Types

Overall, the detailed analysis of systemic issues for each of the facility types reveals little significant difference in systemic issues within the various subsystems with regards to the relative ranking of the subsystems. (The few exceptions to this are discussed in the following subsection.) *Figures 3-12 through 3-16* show the most prevalent issues for each of the facility types[11]. *Figure 3-17* shows the most prevalent issues for all of the facility types combined. It is apparent from this analysis that the results for all of the facilities combined also statistically represents the results for any one facility type. *Table 3-2* summarizes the data contained in the figures by comparing the most prevalent issues among the various facility types.

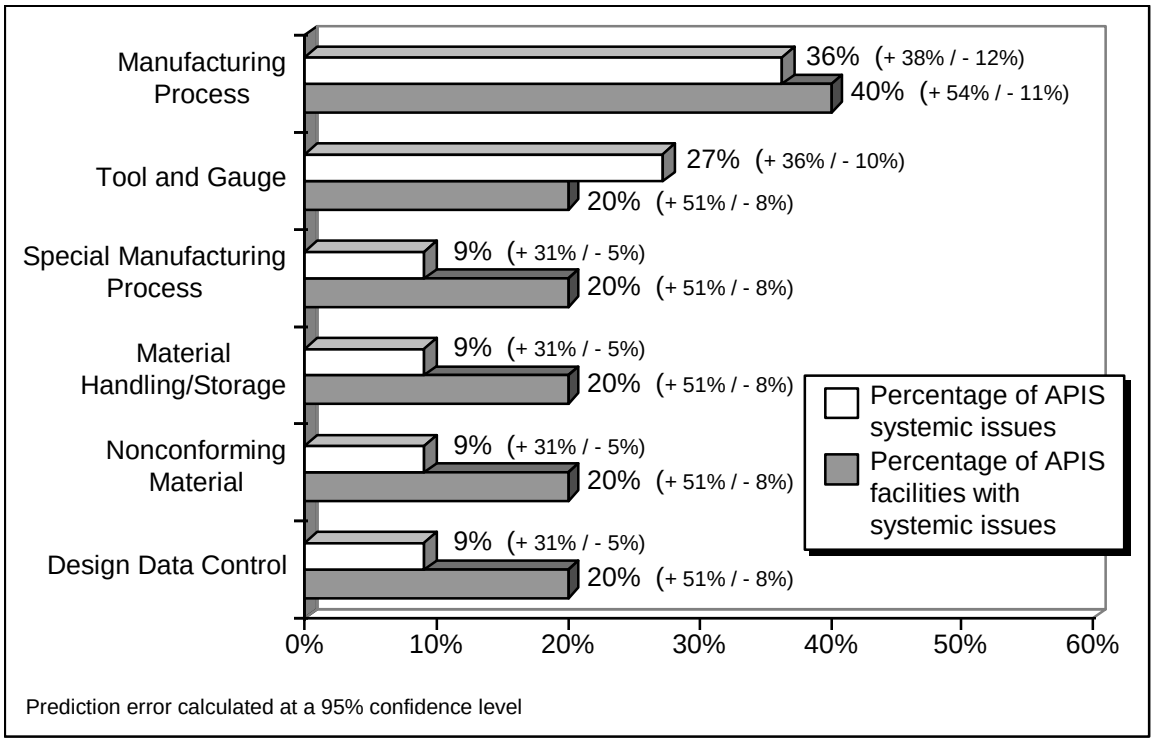

Figure 3-12.—Systemic issues – APIS holders.

[11] The apparently large prediction errors are due to the small number, five, of APIS facilities evaluated. However, the pattern of compliance rates still appears to mirror that of the rest of the industry. See the note in the beginning of this section and *Appendix E* for an explanation of prediction error and its application.

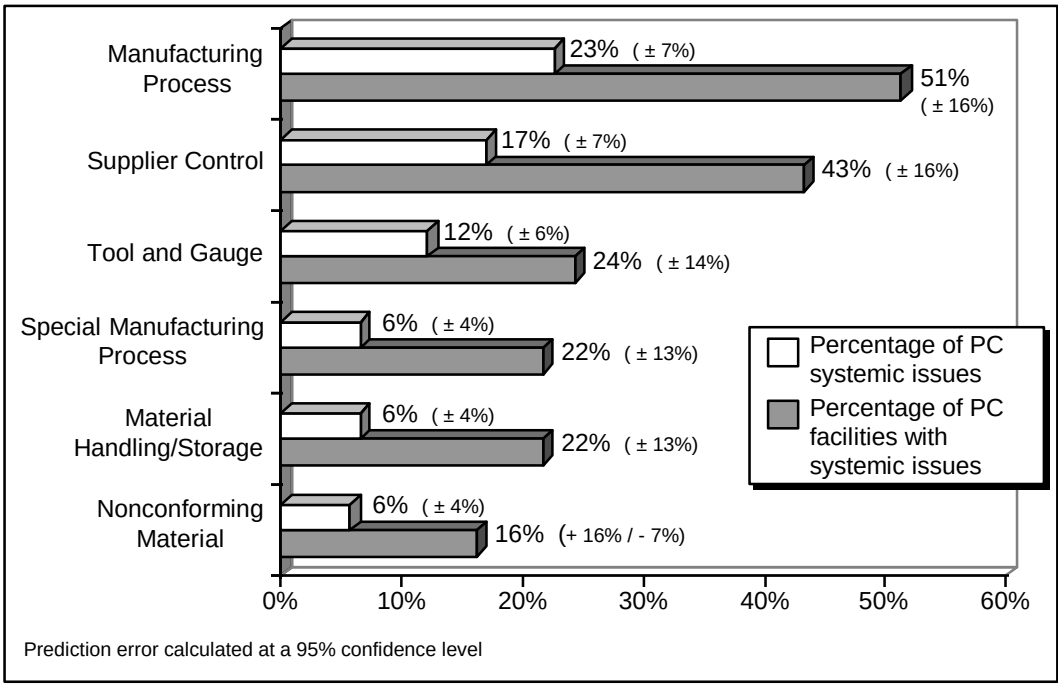

Figure 3-13.—Systemic issues – PC holders.

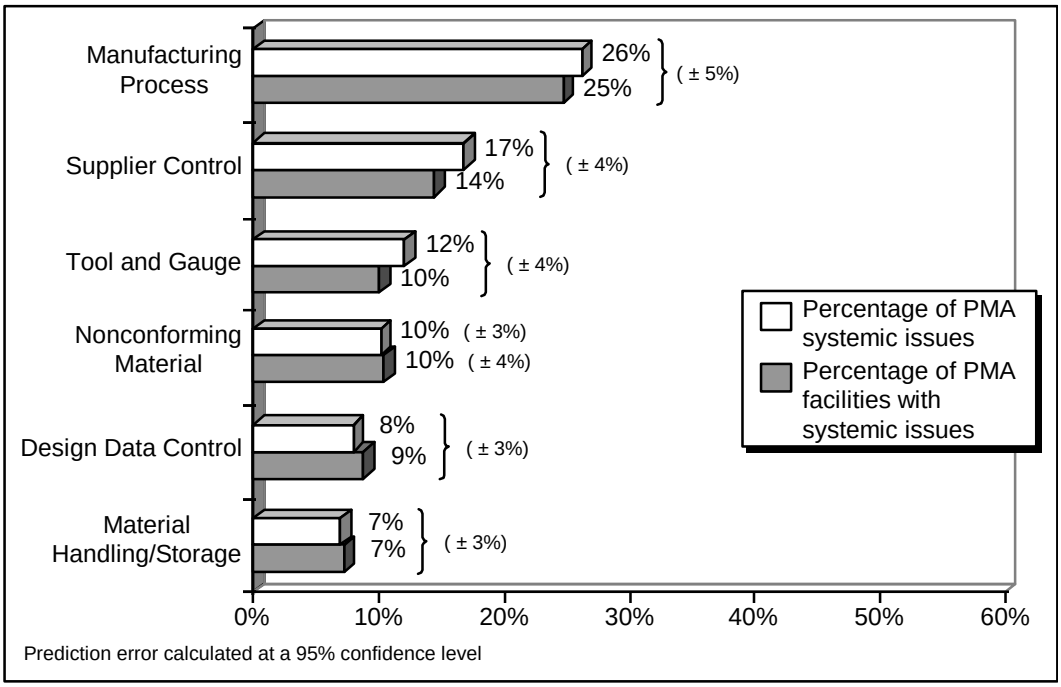

Figure 3-14.—Systemic issues – PMA holders.

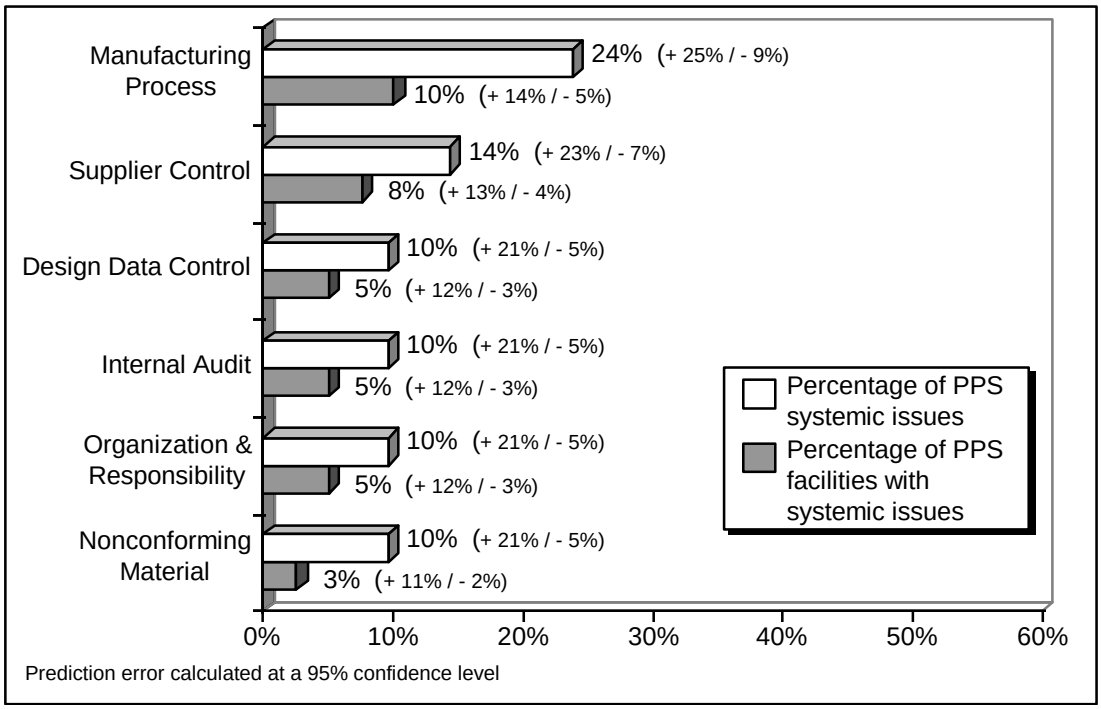

Figure 3-15.—Systemic issues – priority parts suppliers.

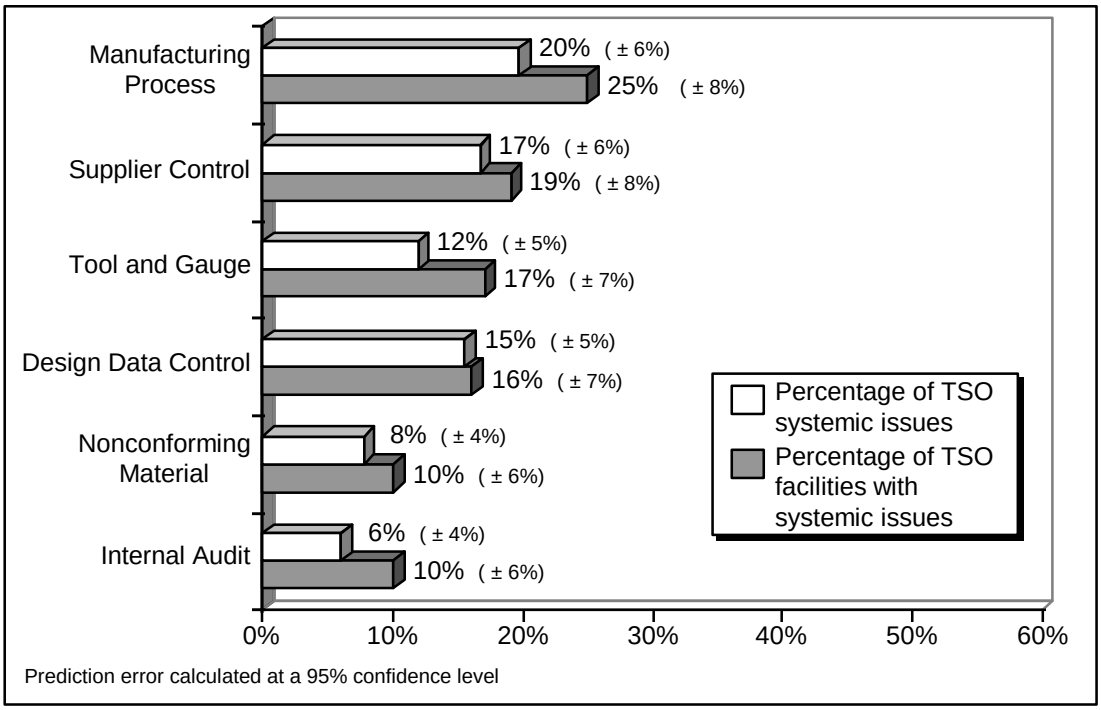

Figure 3-16.—Systemic issues – TSO authorization holders.

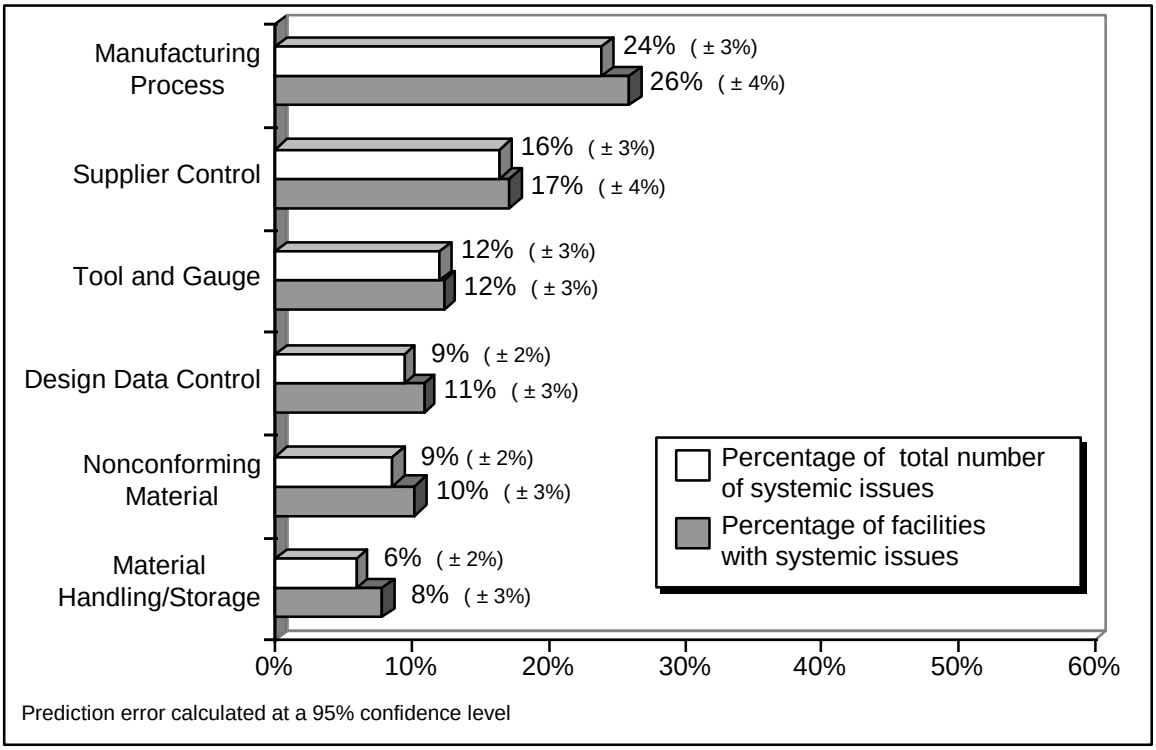

Figure 3-17.—Systemic issues – all facility types.

TABLE 3-2.—Summary of the most prevalent systemic issues

Subsystem	APIS	PC	PMA	PPS	TSO
Manufacturing Processes	✗	✗	✗	✗	✗
Supplier Control		✗	✗	✗	✗
Tool & Gauge	✗	✗	✗		✗
Design Data Control	✗		✗	✗	✗
Special Manufacturing		✗			
Internal Audit				✗ *	
Organization & Responsibility				✗ *	

Leading issues for the industry

✗ = One of the top four systemic issues

* = Tied

A three-year comparison of the most frequently cited subsystems with systemic issues (*see Table 3-3*) indicates that there has been little change in the order of occurrence at the subsystem level for the period FY 1995 to FY 1997. The various types of facilities appear to have similar issues, and also appear to have had the same issues since FY 1995.

TABLE 3-3.—Most frequently cited subsystems with systemic issues – FY 1995 to FY 1997

	Order of Occurrence for Subsystem		
	FY 1995	**FY 1996**	**FY 1997**
ALL FACILITY TYPES			
Manufacturing Process	1	1	1
Supplier Control	2	2	2
Tool and Gauge	4	3	3
Design Data Control	3	4	4
PC			
Manufacturing Process	1	2	1
Supplier Control	2	3	2
Tool and Gauge	3	1	3
PMA			
Manufacturing Process	1	2	1
Supplier Control	2	1	2
Nonconforming Material	5	3	3
Design Data Control	3	5	5
PPS			
Manufacturing Process	1	1	1
Supplier Control	3	2	2
Design Data Control	5	3	3
Tool and Gauge	2	5	7
TSO			
Manufacturing Process	1	1	1
Supplier Control	2	2	2
Design Data Control	3	3	4
Tool and Gauge	5	4	3

3.5.2 Areas of Significant Difference Among Facility Types

There were two occasions in which there were significant[12] dissimilarities, at the subsystem level, among the various facility types regarding the proportion of facilities with systemic issues. They are, in order of precedence:

Facility Type	Subsystem	Description of Divergence
PC Holders	Tool & Gauge	PC holders had a **significantly higher** proportion of facilities with systemic tool & gauge issues than the other facility types.
PC Holders	FAA Reporting Requirements	PC holders had a **significantly higher** proportion of facilities with systemic issues with FAA reporting requirements than the other facility types.

Figures 3-18 and 3-19 graphically demonstrate the significance of these differences.

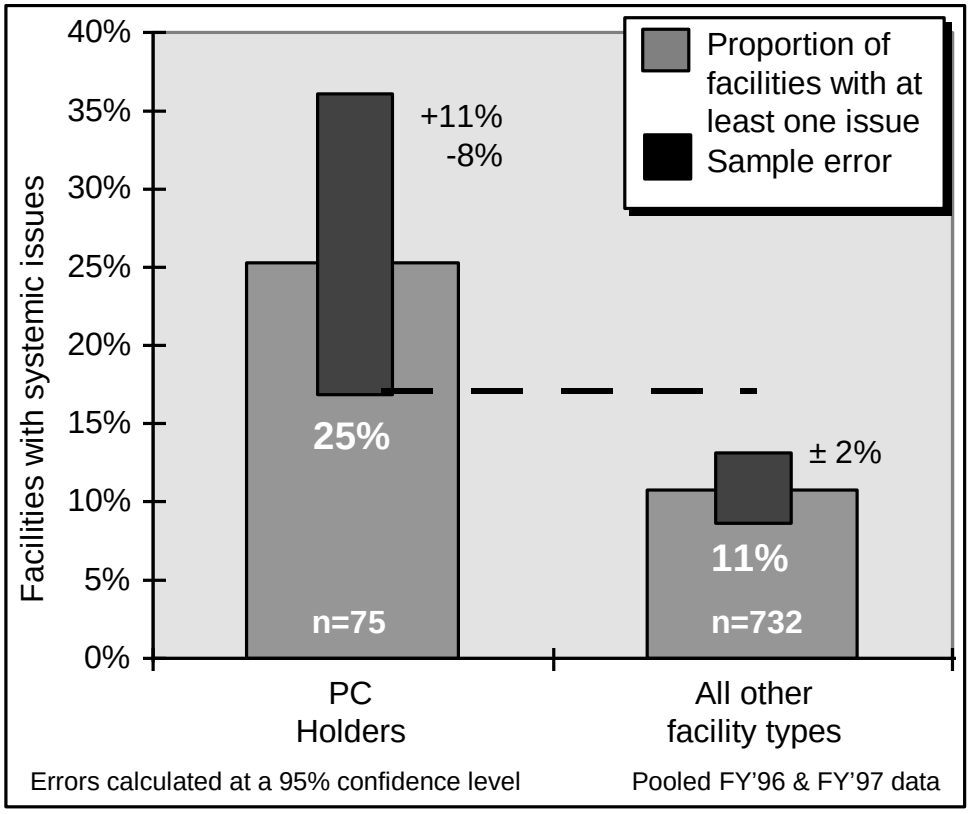

Figure 3-18.—Significant variance in systemic issue incidence rate for tool & gauge.

[12] at a 95 percent confidence level

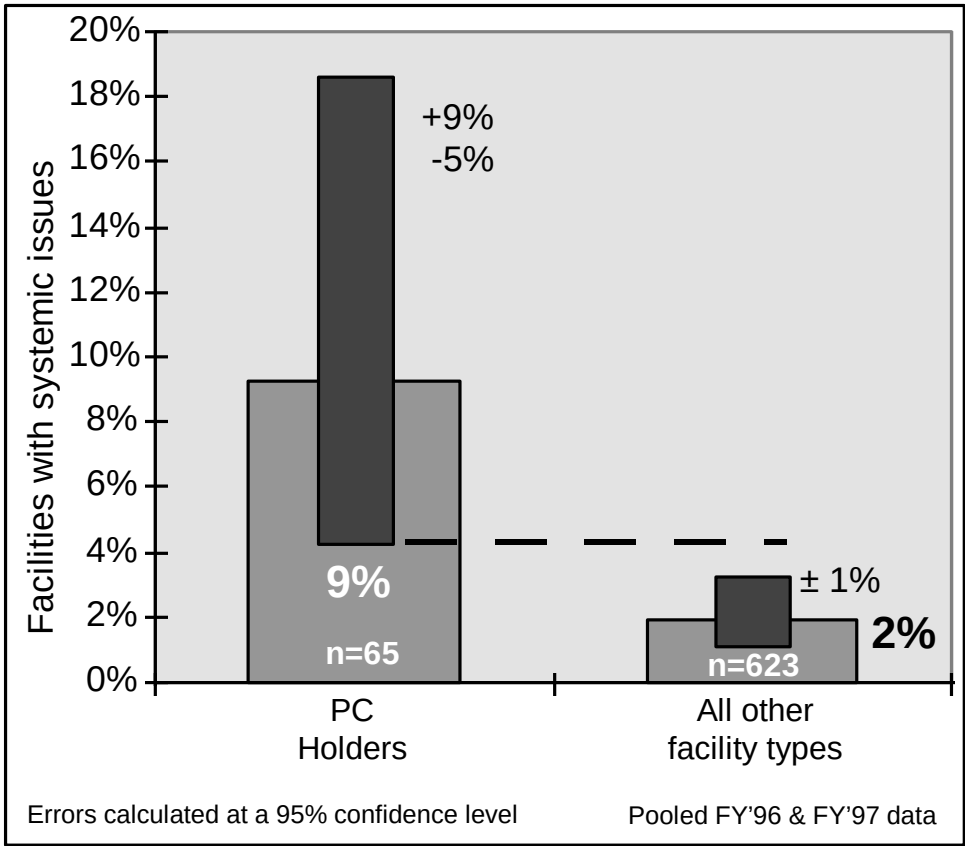

Figure 3-19.—Significant variance in systemic issue incidence rate for FAA reporting requirements.

3.5.3 Facility Perspective

Figures 3-20 through 3-23 compare the probability of facilities having systemic issues before and after adjustment for a subsystem's applicability to the facilities. The earlier charts (*Subsection 3.5.1*) presented the data from an industry perspective. By contrast, the figures in this subsection are more germane to the individual facility types. By adjusting for the applicability of the subsystems within a facility type, subsystems that do not have a wide deployment within a particular facility type may increase in significance.

The gray bars on figures *3-20 through 3-23* present the same data as the gray bars on *figures 3-12 through 3-16* — the percentage of all facilities with systemic issues recorded. That is, the gray bars show the number of facilities within the facility type with systemic issues divided by the number of facilities evaluated within that facility type. The white bars in *figures 3-20 through 3-23* represent the probability of issues at only those facilities in which the subsystems applied. That is, the white bars show the number of facilities within the facility type with systemic issues divided by the number of facilities evaluated within that facility type where the subsystem was found to be applicable. As an example of how this data can be interpreted, we will explore the probability of facilities having

systemic issues within the nondestructive inspection (NDI) subsystem. Referring to the figures presented in *Subsection 3.5.1* (*figures 3-12 through 3-16*), the NDI subsystem did not have enough findings or systemic observations recorded for the year to be considered a top issue for any of the facility types. Therefore, the NDI subsystem does not appear on any of the charts presented in *Subsection 3.5.1*. However, in reviewing *figures 3-20 through 3-23*, nondestructive inspection becomes a significant area for systemic issues. Looking at TSO authorizations, for example, (*figure 3-23*) only three percent of all TSO authorization holders had an issue with NDI (represented by the gray bar). However, those TSO authorizations that had NDI systems in place had a twenty-one percent chance of having systemic issues with those NDI systems (represented by the white bar). This type of presentation of the data allows the reader to focus on those issues relevant to a particular facility with a particular set of capabilities.

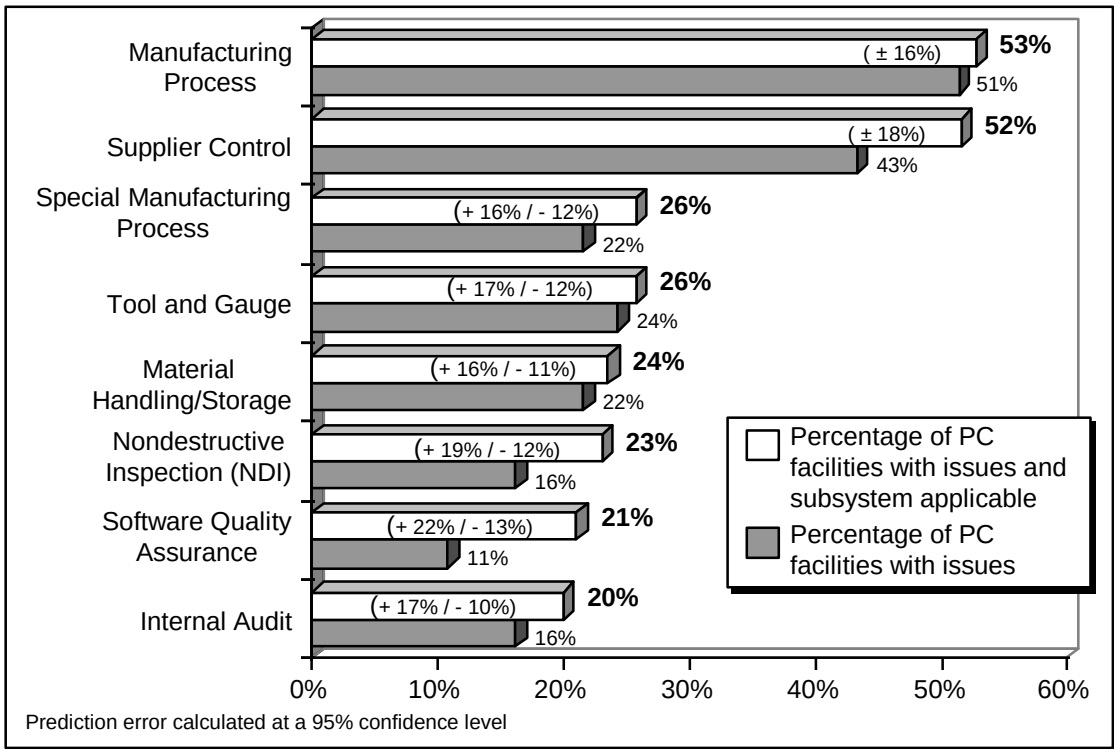

Figure 3-20.—Systemic issues at PC holders adjusted for applicability.

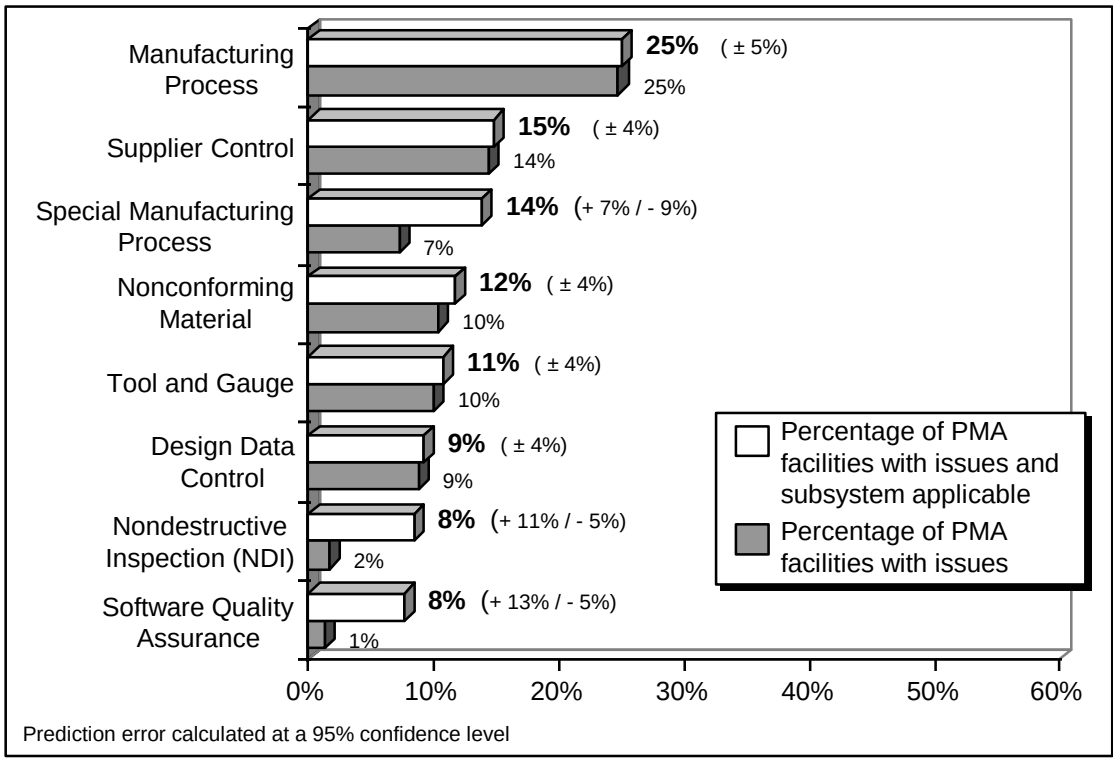

Figure 3-21.—Systemic issues at PMA holders adjusted for applicability.

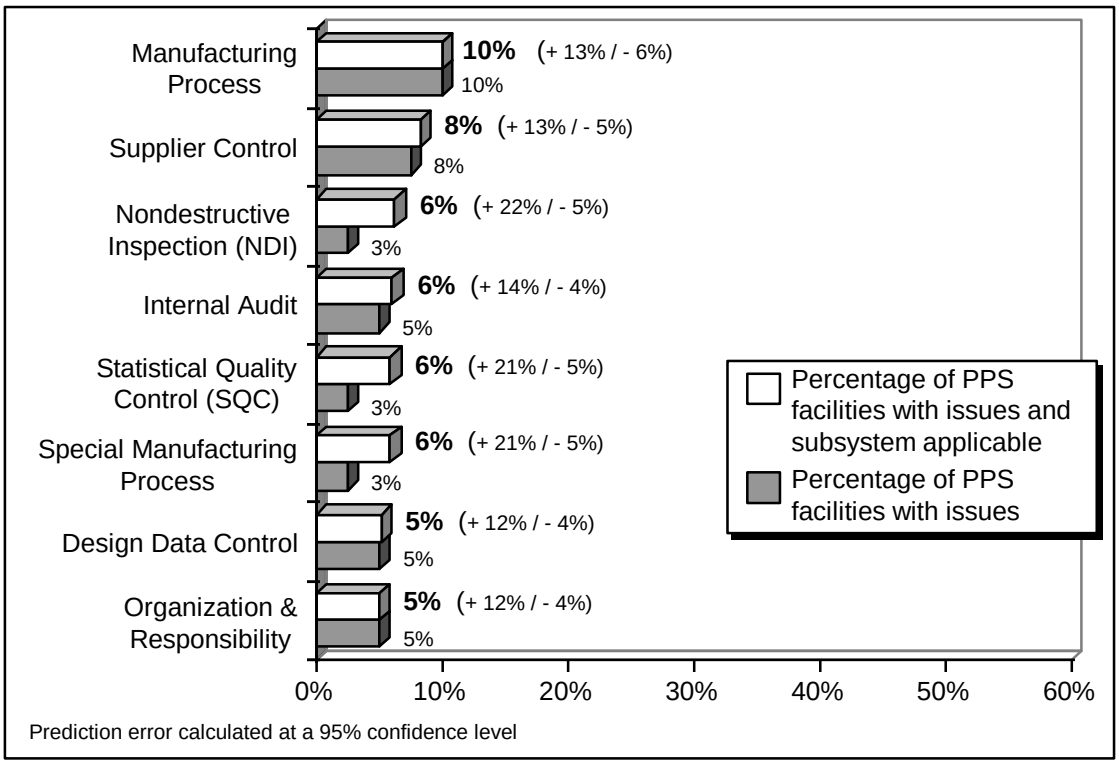

Figure 3-22.—Systemic issues at Priority parts suppliers adjusted for applicability.

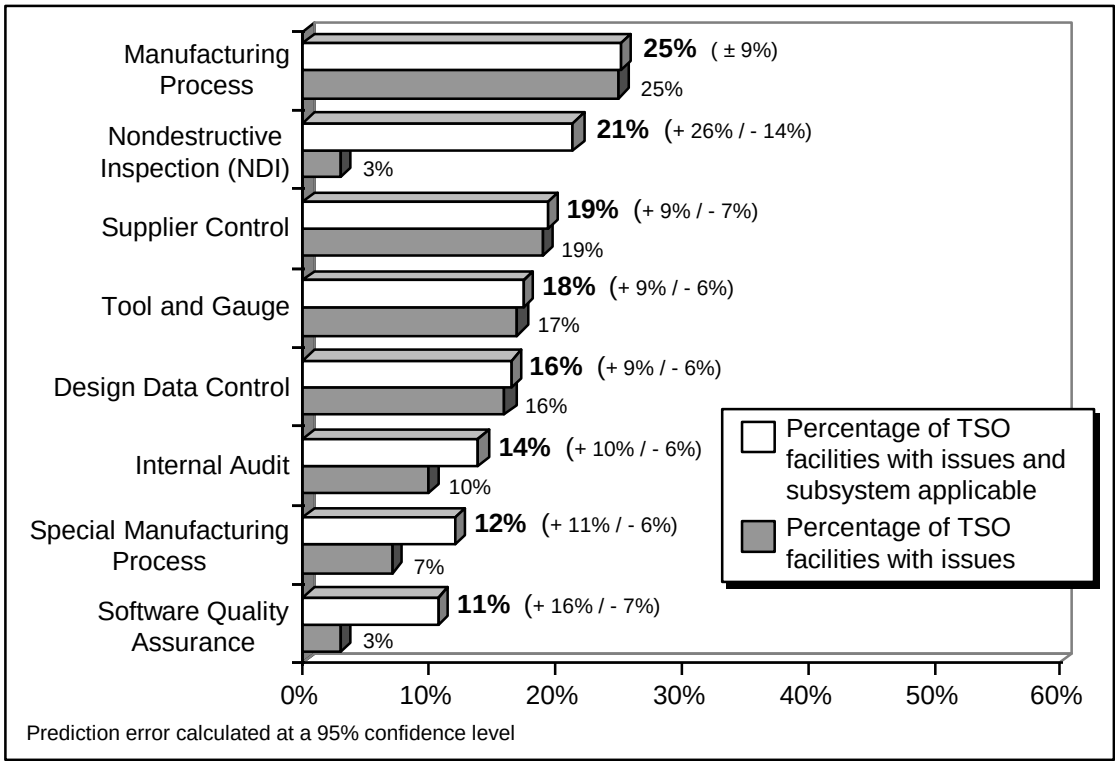

Figure 3-23.—Systemic issues at TSO authorization holders adjusted for applicability.

3.6 Analysis of Evaluation Criteria

The following subsections contain lists of the most significant criteria issues at any given facility type. This data can be used by industry to focus corrective action and by the FAA for resource allocation initiatives. The data is presented in three forms: a view of the industry as a whole listed by type of issue –– systemic, isolated, or FAR-based; a focus on individual facility types in which systemic issues are separated by facility type; and, a summary of comparisons among the facility types. For clarity, only the top issues are reported in these subsections; however, a full listing of this data can be found in *Appendix C*.

Many of the criteria that are the most prevalent for FY 1997 were also the most prevalent issues for FY 1996 and FY 1995. *Tables 3-4 and 3-6* present comparisons of the most prevalent criteria with which systemic and isolated issues occurred over the three-year period. The comparisons are done at the industry level only, i.e., with all facility types combined. With 226 different criteria from which to categorize the various findings and observations, a dilution effect occurs as the data is compared at the criteria level. Dividing the findings and observations still further into facility types reduces their occurrence within the individual criteria to a level too low with which to make reliable comparisons. The lowest level these types of comparisons can be reliably made is at the industry level. A three-year comparison of FAR-based observations is not presented due to their rarity, making such a comparison unrealistic.

3.6.1 A View of the Industry

This subsection lists the most prevalent criteria issues within the industry as a whole. The data from all of the ACSEP evaluations performed in FY 1997 are pooled together. The table column titled “Percent of Domestic Facilities” presents the proportion of facilities evaluated that had findings and/or observations recorded. This presentation of the data is similar to that in *Subsection 3.5.1,* i.e., an analysis of the data with an industry perspective. The column titled “Percent of Applicable Facilities with Issues” provides the frequency of findings and/or observations reported at those facilities where the criteria was implemented. This type of presentation of the data is similar to that made for the subsystems in *Subsection 3.5.3*. As an example of this type of data, refer to the fourth row of *Table 3-4* (criteria 5Q3). This row indicates that twenty-one systemic issues were recorded for this criteria in FY 1997 – three percent of all issues recorded in FY 1997. Additionally, five percent of all of the facilities evaluated were discovered to have issues with criteria. However, this percentage includes facilities where this criteria did not apply. In those facilities where the criteria did apply, nine percent had systemic issues with this criteria. In other words, whereas five percent of all facilities had systemic issues with performing special processes in accordance with process specifications, nine percent of the facilities that were actually performing special processes had systemic issues with following the process specifications.

3.6.1.1 Systemic Findings and Observations

The 21 evaluation criteria most frequently rated as systemic are presented in *Table 3-4.* These criteria accounted for more than one-half of all findings and systemic observations. As a group, they occurred at 78 percent of the facilities with systemic issues.

TABLE 3-4.—Predominant systemic findings and observations

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Domestic Facilities	Percent of Applicable Facilities with Issues
1	15M1	Internal auditing program	30	5%	7%	10%
2	10Q1	Initial & periodic evaluations of suppliers	30	5%	7%	9%
3	4P9	Completed product/part identification	29	5%	7%	7%
4	5Q3	Accord with process specifications	21	3%	5%	9%
5	4M1	Operation within production limitations	17	3%	4%	4%
6	11Q1	Control of nonconforming products	17	3%	4%	4%
7	10Q5	Flow down of technical & quality requirements	16	3%	4%	5%
8	10Q10	Receiving inspection	16	3%	4%	4%
9	4Q5	Inspection records	16	3%	4%	4%
10	4P4	Work instructions control manufacturing processes	15	2%	3%	4%
11	12Q3	Storage of conforming parts	15	2%	3%	4%
12	11Q2	Permanent identification of scrap material	14	2%	3%	4%
13	4Q1	Inspection methods and plans	14	2%	3%	4%
14	11Q4	Material review record generated	13	2%	3%	4%
15	10Q2	Use of approved suppliers	13	2%	3%	3%
16	7Q12	Calibration records	13	2%	3%	3%
17	12Q5	Identification of age control products	11	2%	3%	4%
18	7Q3	Tool & gauge recall system	11	2%	3%	3%
19	10Q8	Verification of raw material	11	2%	3%	3%
20	7Q1	Approval/inspection of tools & gauges	11	2%	3%	3%
21	4Q12	Completion of all inspections & tests	11	2%	3%	3%

As *Table 3-5* illustrates, many of the most significant systemic issues have been so for the last three years. The table lists all of the criteria that have been within the top tenth percentile for each of the years from FY 1995 to FY 1997. The criteria are ranked by their significance over the three-year period. The columns "FY 1997," "FY 1996," and "FY 1995" indicate whether the criteria was a top issue for that year. Of the twenty criteria listed, twelve were top issues in at least two of the three years listed.

TABLE 3-5.—Three-year trend of most predominant systemic issues – by criteria

3-Year Rank	Criteria		FY 1997	FY 1996	FY 1995
1	10Q1	Initial & periodic evaluations of suppliers	✗	✗	✗
2	4P9	Completed product/part identification	✗	✗	✗
3	15M1	Internal auditing program	✗	✗	✗
4	11Q1	Control of nonconforming products	✗	✗	✗
5	10Q10	Receiving inspection	✗	✗	✗
6	4P4	Work instructions control manufacturing processes	✗		✗
7	10Q2	Use of approved suppliers		✗	✗
8	5Q3	Accord with process specifications	✗	✗	
9	10Q5	Flow down of technical & quality requirements	✗		✗
10	11Q2	Permanent identification of scrap material	✗	✗	
11	12Q7	Control of product removal/issuance		✗	
12	12Q3	Storage of conforming parts	✗	✗	
13	10Q8	Verification of raw material		✗	
14	4Q5	Inspection records	✗		✗
15	4M1	Operation within production limitations	✗		
16	7Q1	Approval/inspection of tools & gauges			✗
17	2E1	Design change approval			✗
18	4Q1	Inspection methods and plans			✗
19	2E2	Drawing control system			✗
20	10Q12	Records of receiving inspection		✗	

✗ Criteria within the top tenth percentile for the fiscal year

"blank" Criteria within the lower 90th percentile for the fiscal year

3.6.1.2 Isolated Observations

The 17 evaluation criteria most frequently rated isolated observations presented in *Table 3-6* accounted for more than one-half of all isolated observations. As a group, they occurred in some combination at 70 percent of the facilities with isolated issues.

TABLE 3-6.—*Predominant isolated observations*

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Domestic Facilities	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	12	6%	3%	4%
2	11Q2	Permanent identification of scrap material	11	5%	3%	3%
3	12Q5	Identification of age control products	10	5%	2%	3%
4	11Q1	Control of nonconforming products	10	5%	2%	3%
5	15M1	Internal auditing program	9	4%	2%	3%
6	2E1	Design change approval	8	4%	2%	2%
7	7Q1	Approval/inspection of tools & gauges	8	4%	2%	2%
8	4P4	Work instructions control manufacturing processes	6	3%	1%	2%
9	2E2	Drawing control system	6	3%	1%	2%
10	10Q5	Flow down of technical & quality requirements	5	2%	1%	1%
11	7Q14	Identification of gauges	5	2%	1%	1%
12	4P9	Completed product/part identification	5	2%	1%	1%
13	4Q5	Inspection records	5	2%	1%	1%
14	7Q3	Tool & gauge recall system	4	2%	1%	1%
15	2E7	Design/Technical data document control	4	2%	1%	1%
15	4Q1	Inspection methods and plans	4	2%	1%	1%
16	12Q3	Storage of conforming parts	4	2%	1%	1%

As *Table 3-7* illustrates, many of the most significant isolated observations have been so for the last three years. The table lists all of the criteria that have been within the top tenth percentile for each of the years from FY 1995 to FY 1997. The criteria are ranked by their significance over the three-year period. The columns "FY 1997," "FY 1996," and "FY 1995" indicate whether the criteria was a top issue for that year. Of the fifteen criteria listed, nine were top issues in at least two of those years listed. It should be noted that all but four of the top fifteen isolated observations listed below are also listed as top systemic issues in *Table 3-5*, reinforcing the conclusion made in *Section 3.3* that isolated observations are somehow correlated with systemic issues.

TABLE 3-7.—Three-year trend of most predominant isolated observations – by criteria

3-Year Rank	Criteria		FY 1997	FY 1996	FY 1995
1	12Q5	Identification of age control products	✗	✗	✗
2	15M1	Internal auditing program	✗	✗	✗
3	10Q1	Initial & periodic evaluations of suppliers	✗	✗	✗
4	4P4	Work instructions control manufacturing processes	✗	✗	✗
5	2E7	Design/Technical data document control		✗	✗
6	7Q1	Approval/inspection of tools & gauges	✗		✗
7	11Q1	Control of nonconforming products	✗	✗	
8	4Q5	Inspection records		✗	✗
9	2E2	Drawing control system			✗
10	5Q3	Accord with process specifications		✗	
11	4Q3	Issuance of inspection stamps		✗	
12	2E1	Design change approval	✗		
13	11Q2	Permanent identification of scrap material	✗		✗
14	10Q2	Use of approved suppliers		✗	
15	4Q12	Completion of all inspections & tests		✗	

✗ Criteria within the top tenth percentile for the fiscal year

"blank" Criteria within the lower 90th percentile for the fiscal year

3.6.1.3 FAR-based Observations

The 11 evaluation criteria with the greatest number of FAR-based observations presented in *Table 3-8* accounted for 60 percent of all FAR-based observations. As a group, these few criteria occurred in some combination at nearly two-thirds of the facilities with FAR-based observations. These criteria should be considered during the review of an approval holder's data (e.g., quality system procedures) prior to acceptance by the FAA.

TABLE 3-8.—*Predominant FAR-based observations*

Rank	Criteria	Description	Number of FAR-based Observations	Percent of Total FAR-based Observations	Percent of Domestic Facilities	Percent of Applicable Facilties with Issues
1	4Q2	Location of inspection stations	4	10%	0.9%	1%
2	2C1	Minor design change approval	3	8%	0.7%	1%
3	1Q6	Record retention schedule	3	8%	0.7%	1%
4	2C5	New TSOA for major design changes	2	5%	0.5%	2%
5	5E1	All special processes in use identified	2	5%	0.5%	1%
6	2E8	Major/minor design changes	2	5%	0.5%	1%
7	10Q8	Verification of raw material	2	5%	0%	1%
8	4M1	Operation within production limitations	2	5%	0.5%	1%
9	1Q1	Quality organizations described	2	5%	0.5%	1%
10	4P9	Completed product/part identification	2	5%	0.5%	0.5%
11	8E3	Approval flight checkoff form	1	3%	0.2%	4%

A year-to-year comparison of FAR-based observations at the criteria level would be inappropriate. Due to the relatively infrequent occurrence of FAR-based observations, and the shear number of possible criteria to categorize them, 226 criteria in total, the number of observations in any given criteria for a year is very small. Considerable variation in the data would result merely from the small sample size being analyzed, and would not be indicative of any trends. It should be noted, however, that at the subsystem level, supplier control, manufacturing processes, and tool & gauge are the three most common subsystems for FAR-based for each of the three years FY 1995 to FY 1997.

3.6.2 A Facility Focus

This subsection lists the criteria issues separated by facility type. Only that data specific to the particular facility type referenced in the table caption is used in the frequency calculations. This allows the reader to use these tables to focus on the issues pertinent to a particular facility type without bias from the other facility types. For example, the data from the relatively few PC holders is not skewed by the data from the much larger population of PMA holders.

As in the previous subsection, the table column titled "Percent of Domestic Facilities" represents the proportion of facilities evaluated that had findings and/or observations recorded. The column titled "Percent of Applicable Facilities with Issues" provides the frequency of findings and/or observations reported at those facilities where the criteria was implemented, and is therefore weighted for applicability of the specific criteria, i.e., it represents only those facilities where the criteria has been implemented. This column compares those criteria that are not widely utilized throughout the industry on a level playing field with those criteria that are universally implemented.

3.6.2.1 Systemic Findings and Observations

Tables 3-9 to 3-12 separate systemic findings and systemic observations by facility type. For clarity, only the top issues are reported in these subsections; however, a full listing of the data can be found in *Appendix C*. Even though only 20 percent of the criteria are reported in these four tables, a total of 60 percent of all systemic issues are represented.

TABLE 3-9.—*Predominant systemic findings and observations — PC holders*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for PC Holders	Percent of PC Facilities	Percent of Applicable Facilities with Issues
1	4Q1	Inspection methods and plans	7	6%	19%	21%
2	10Q1	Initial & periodic evaluations of suppliers	6	5%	16%	21%
3	15M1	Internal auditing program	6	5%	16%	20%
4	10Q5	Flow down of technical & quality requirements	4	3%	11%	15%
5	10Q10	Receiving inspection	4	3%	11%	14%
6	5E1	All special processes in use identified	4	3%	11%	13%
7	7Q3	Tool & gauge recall system	4	3%	11%	13%
8	4P4	Work instructions control manufacturing processes	4	3%	11%	12%
9	9Q3	NDI procedures/specifications available & used	3	2%	8%	12%
10	5Q3	Accord with process specifications	3	2%	8%	11%
11	11Q1	Control of nonconforming products	3	2%	8%	9%
12	4Q5	Inspection records	3	2%	8%	9%
12	12Q5	Identification of age control products	3	2%	8%	9%
13	4E1	Accord with FAA-approved design data	3	2%	8%	9%
14	9E2	Control of NDI processes & changes	2	2%	5%	8%
15	10Q6	Quality Assurance review of purchase documents	2	2%	5%	7%
16	12Q2	Special environmental controls	2	2%	5%	7%
17	1M1	Overall policy document	2	2%	5%	6%
17	8E1	Test procedures/instructions established	2	2%	5%	6%
17	12Q3	Storage of conforming parts	2	2%	5%	6%
18	7Q16	Inaccurate tools & gauges identified	2	2%	5%	6%
19	7Q1	Approval/inspection of tools & gauges	2	2%	5%	6%
20	2E7	Design/Technical data document control	2	2%	5%	6%
21	4M1	Operation within production limitations	2	2%	5%	6%

TABLE 3-10.—*Predominant systemic findings and observations — PMA holders*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for PMA Holders	Percent of PMA Facilities	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	24	8%	10%	10%
2	10Q1	Initial & periodic evaluations of suppliers	15	5%	6%	8%
3	15M1	Internal auditing program	12	4%	5%	8%
4	5Q3	Accord with process specifications	11	3%	4%	9%
5	4M1	Operation within production limitations	11	3%	4%	5%
6	12Q3	Storage of conforming parts	11	3%	4%	5%
7	11Q1	Control of nonconforming products	10	3%	4%	4%
8	11Q2	Permanent identification of scrap material	9	3%	4%	5%
9	7Q12	Calibration records	9	3%	4%	4%
10	10Q8	Verification of raw material	9	3%	4%	4%
11	4Q5	Inspection records	9	3%	4%	4%
12	11Q4	Material review record generated	8	3%	3%	4%
13	10Q5	Flow down of technical & quality requirements	8	3%	3%	4%
14	10Q10	Receiving inspection	8	3%	3%	3%
15	12Q5	Identification of age control products	6	2%	2%	4%
16	4P5	Work instruction revision approval	6	2%	2%	3%
17	5Q2	Required qualifications/approvals	5	2%	2%	4%
18	4P4	Work instructions control manufacturing processes	5	2%	2%	2%
19	4P2	Work instructions prepared	5	2%	2%	2%
20	10Q2	Use of approved suppliers	5	2%	2%	2%
21	2E7	Design/Technical data document control	5	2%	2%	2%
22	7Q1	Approval/inspection of tools & gauges	5	2%	2%	2%

TABLE 3-11.—*Predominant systemic findings and observations — priority parts suppliers*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for Suppliers	Percent of Supplier Facilities	Percent of Applicable Facilities with Issues
1	15M1	Internal auditing program	2	10%	5%	6%
2	9E1	Engineering review of NDI processes	1	5%	3%	7%
3	6Q1	Statistical sampling inspection plans	1	5%	3%	6%
4	5Q3	Accord with process specifications	1	5%	3%	6%
5	2E3	Technical data change approval	1	5%	3%	5%
6	4M1	Operation within production limitations	1	5%	3%	5%
7	10Q1	Initial & periodic evaluations of suppliers	1	5%	3%	4%
8	10Q7	Action on problem notification	1	5%	3%	4%

TABLE 3-12.—*Predominant systemic findings and observations — TSO authorization holders*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for TSO Holders	Percent of TSO Facilities	Percent of Applicable Facilities with Issues
1	15M1	Internal auditing program	10	6%	10%	14%
2	10Q1	Initial & periodic evaluations of suppliers	8	5%	8%	10%
3	2C4	Data submittal for TSO minor changes	7	4%	7%	8%
4	5Q3	Accord with process specifications	6	4%	6%	11%
5	10Q2	Use of approved suppliers	6	4%	6%	7%
6	4Q12	Completion of all inspections & tests	6	4%	6%	6%
7	2C1	Minor design change approval	5	3%	5%	7%
8	10Q5	Flow down of technical & quality requirements	4	2%	4%	5%
9	4P4	Work instructions control manufacturing processes	4	2%	4%	4%
10	10Q10	Receiving inspection	4	2%	4%	4%
11	1Q4	Quality Manual	4	2%	4%	4%
12	11Q4	Material review record generated	3	2%	3%	4%
13	10Q6	Quality Assurance review of purchase documents	3	2%	3%	4%
14	7Q3	Tool & gauge recall system	3	2%	3%	3%
15	11Q2	Permanent identification of scrap material	3	2%	3%	3%
16	1Q6	Record retention schedule	3	2%	3%	3%
17	7Q1	Approval/inspection of tools & gauges	3	2%	3%	3%
18	11Q1	Control of nonconforming products	3	2%	3%	3%
19	2E2	Drawing control system	3	2%	3%	3%
20	2E9	Technical data file	3	2%	3%	3%
20	4P9	Completed product/part identification	3	2%	3%	3%
21	4E1	Accord with FAA-approved design data	3	2%	3%	3%
21	4M1	Operation within production limitations	3	2%	3%	3%
21	4Q5	Inspection records	3	2%	3%	3%

3.6.2.2 Isolated Observations

Tables 3-13 to 3-16 separate isolated observations by facility type. For clarity, only the top issues are reported in these tables; however, a full listing of the data can be found in *Appendix C*. Even though only 10 percent of the criteria are reported in these four tables, a total of nearly one-half of all isolated observations are represented.

TABLE 3-13.—*Predominant isolated observations — PC holders*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All PC Holders	Percent of PC Facilities	Percent of Applicable Facilities with Issues
1	12Q5	Identification of age control products	6	9%	16%	18%
2	10Q1	Initial & periodic evaluations of suppliers	5	7%	14%	17%
3	11Q1	Control of nonconforming products	3	4%	8%	9%
4	6Q1	Statistical sampling inspection plans	2	3%	5%	12%
5	7Q10	Control of NDI Equipment	2	3%	5%	8%
6	5Q4	Records maintained	2	3%	5%	7%
7	15M1	Internal auditing program	2	3%	5%	7%
8	11Q3	MRB established and operational	2	3%	5%	6%
9	12Q3	Storage of conforming parts	2	3%	5%	6%
10	2E1	Design change approval	2	3%	5%	6%
11	2E2	Drawing control system	2	3%	5%	6%
12	1Q5	Tags, forms, etc., described	2	3%	5%	6%
12	2E7	Design/Technical data document control	2	3%	5%	6%

TABLE 3-14.—*Predominant isolated observations — PMA holders*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All PMA Holders	Percent of PMA Facilities	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	5	9%	2%	3%
2	7Q1	Approval/inspection of tools & gauges	5	9%	2%	2%
3	15M1	Internal auditing program	4	7%	2%	3%
4	4P9	Completed product/part identification	4	7%	2%	2%
5	12Q5	Identification of age control products	3	6%	1%	2%
6	10Q1	Initial & periodic evaluations of suppliers	3	6%	1%	2%
7	10Q5	Flow down of technical & quality requirements	2	4%	1%	1%
8	7Q14	Identification of gauges	2	4%	1%	1%
9	2E1	Design change approval	2	4%	1%	1%
10	2E7	Design/Technical data document control	2	4%	1%	1%
11	11Q1	Control of nonconforming products	2	4%	1%	1%

TABLE 3-15.—*Predominant isolated observations — priority parts suppliers*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All Suppliers	Percent of Priority Parts Supplier Facilities	Percent of Applicable Facilities with Issues
1	3BE1	Software Configuration Management Plan	1	7%	3%	14%
2	5Q3	Accord with process specifications	1	7%	3%	6%
3	2E1	Design change approval	1	7%	3%	5%
4	10Q1	Initial & periodic evaluations of suppliers	1	7%	3%	4%

TABLE 3-16.—*Predominant isolated observations — TSO authorization holders*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All TSO Holders	Percent of TSO Holders	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	5	8%	5%	6%
2	11Q1	Control of nonconforming products	5	8%	5%	5%
3	4Q5	Inspection records	4	6%	4%	4%
4	10Q1	Initial & periodic evaluations of suppliers	3	5%	3%	4%
5	7Q3	Tool & gauge recall system	3	5%	3%	3%
6	4P4	Work instructions control manufacturing processes	3	5%	3%	3%
7	2E1	Design change approval	3	5%	3%	3%
8	2E2	Drawing control system	3	5%	3%	3%

3.6.3 Summary of Criteria Issues

A comparative analysis was performed on the criteria with the highest number of findings and systemic observations, i.e., those with industry-wide or facility-type specific systemic issues at greater than seven percent of the facilities. This type of analysis highlights differences among the various facility types. *Figure 3-24* projects how the various facility types compare to the rest of the industry in the top 14 systemic issues. The reader can use this chart in order to focus on individual areas of concern and compare performance to the rest of the aviation community.

Criteria		PC	PMA	PPS	TSO
10Q1	Initial & periodic evaluation of suppliers				
15M1	Internal auditing program				
4P9	Completed product/part identification		⇧		
11Q1	Control of nonconforming products				
5Q3	Accord with process specifications				
10Q10	Receiving Inspection	⇧			
11Q2	Permanent identification of scrap material				
10Q2	Use of approved suppliers				⇧
4M1	Operation within production limitations			n/a	
10Q5	Flow down of technical & quality requirements	⇧			
4Q1	Inspection methods and plans	⇧			
8E1	Test procedures/instructions established			⇧	
2C1/ 2C4	Minor design change approval			n/a	⇧
1M5	Policy document review	⇧			

⇧ Significantly higher than industry average
⇧ Slightly higher than industry average
⇩ Slightly lower than industry average
⇩ Significantly lower than industry average
"Blank" Consistent with industry average
n/a Insufficient data to make determination

Figure 3-24.—Comparison of systemic issues for the various facility types.

3.7 Trend Analysis

ACSEP evaluation results have been collected in a standard and consistent manner sufficient to allow trend analysis since FY 1995. Since only three years of data are available, only preliminary analysis can be performed. At least two more years of data will be needed before any conclusive trend analysis can be reported. Notwithstanding, this report presents the preliminary trend analysis for consideration. The reader is, however, cautioned against placing too much reliance on any suggested trends from such a small sample.

The figures presented contain the raw proportion of facilities that had at least one observation or finding for each of the given fiscal years. The facility data is not adjusted for the differences in system and process complexity among the various facility types. Therefore, the data for each facility type should be considered separately; and no comparison of the facility types can be made. A 90 percent confidence level was used in all cases to determine if a preliminary trend was indicated (an explanation as to the selection of the confidence level is discussed further in *Appendix E*).

3.7.1 Systemic Issues

Most of the data from the various facility types and the overall trend of systemic issues appear to be consistently flat over the last three years. There are only two exceptions where there may be a developing trend: that for PC holders and priority parts suppliers. The results of the preliminary trend analysis of systemic issues is presented in *figure 3-25*.

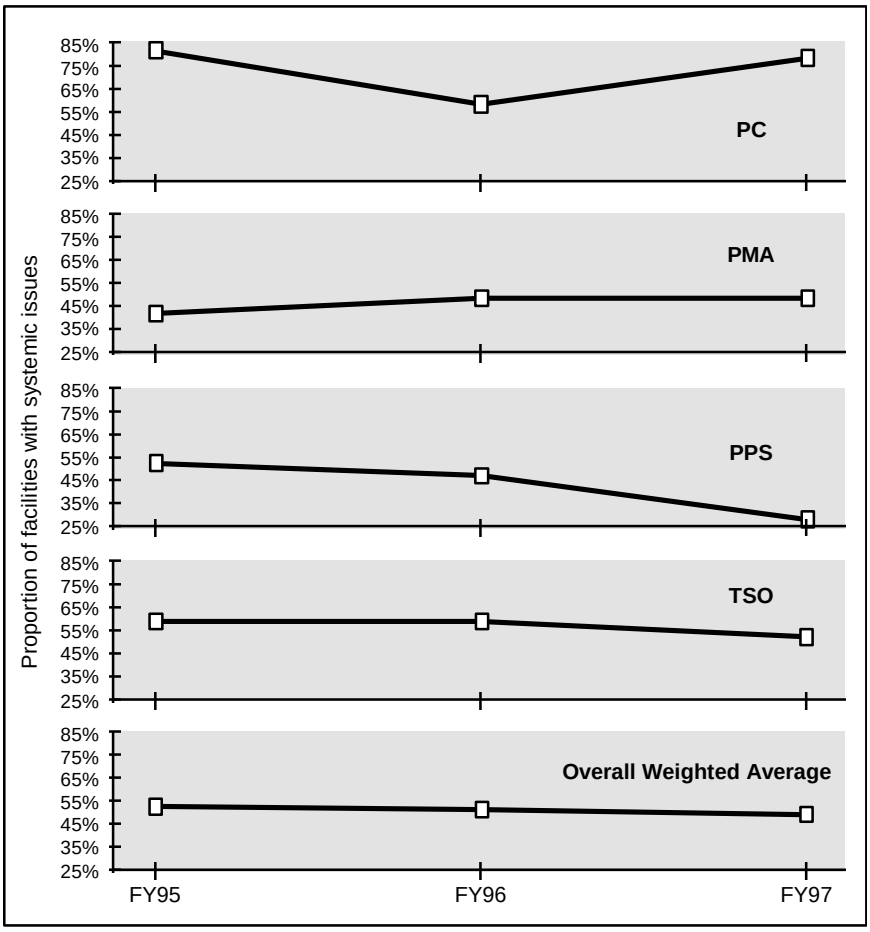

Figure 3-25.—Preliminary trend data for systemic issues.

The data for PC holders appears to have an annual cyclical fluctuation. As reported in *Subsection 3.4.2* in this report, this fluctuation in the proportion of PC holders with systemic issues appears to be caused by a sampling bias introduced at the inception of ACSEP. Due to the relatively small number of PC holders, and the relative critical nature of these facilities, it is theorized that the initial selection of facilities to evaluate was not random. Additionally, since each PC holder is re-evaluated every two years, there is no variation in the biannual cycle of facility selection for evaluation. The other facility types would be far less affected by the initial selection for two reasons. First, the greater number of facilities in the other facility types lessens the impact that targeted selection of a few facilities would have on an otherwise random selection of facilities. Secondly, at the

inception of the program, less than half of the other facilities were evaluated in the first year causing a number of these facilities to be evaluated at varying frequencies. This causes facilities that were initially evaluated in the same year to not be evaluated as a group in subsequent years as the program matures. For these reasons, it is theorized that the evaluation of PC holders in a given year is not random, and the selection of the other facility types is random. Random selection of the facilities is essential in order to use the data to project results with statistical analysis.

The other area where there appears to be a trend is the data for priority parts suppliers. There is the possibility of a downward trend in systemic issues. However, for the reasons stated in *Section 3.7*, this analysis is still considered preliminary. There is still a ten percent chance that the downward trend is nothing more than the normal variation in sample data. Additional data will be needed before any defensible conclusions can be made.

3.7.2 Isolated Observations

With the exception of PMA facilities, the individual facility types had neither upward nor downward trending to their occurrence of isolated observations. The data suggests the possibility of a downward trend over the last three years for isolated observations. The overall weighted average also trends down due in most part to the high ratio of PMA facilities in the overall numbers. As stated earlier, there is a one in ten chance that the trend seen in the PMA facility data is the simple result of normal sample variation. The results of the preliminary trend analysis of isolated observations are presented in *figure 3-26*.

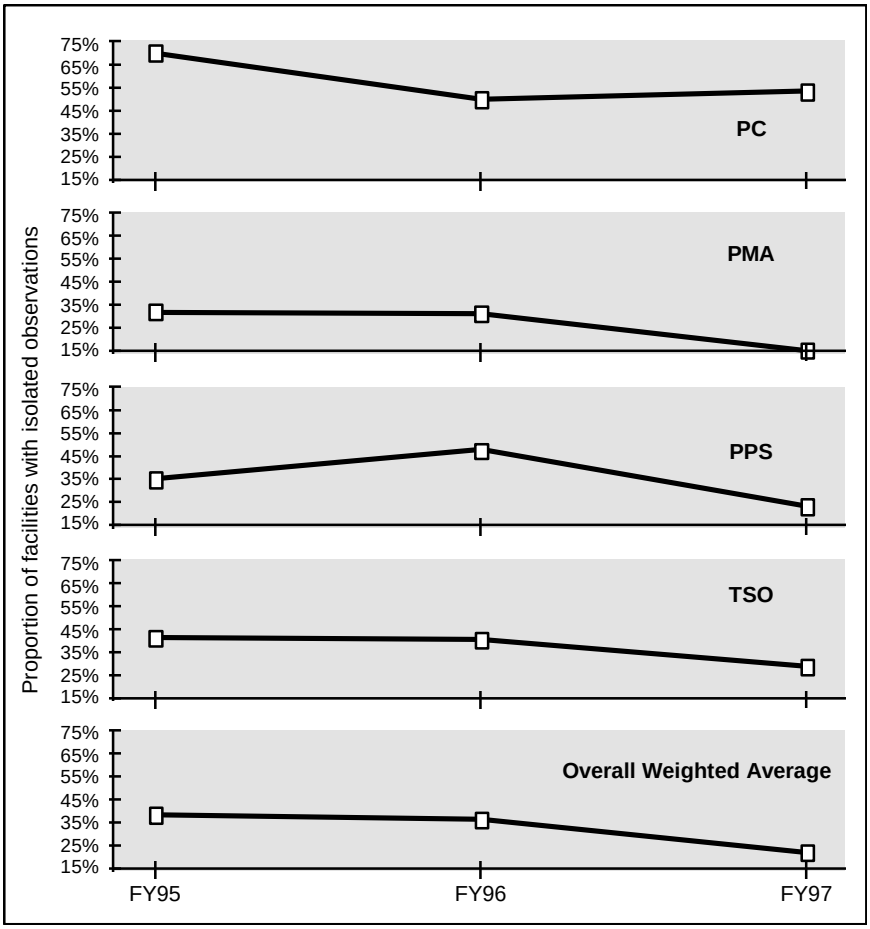

Figure 3-26.—Preliminary trend data for isolated observations.

3.7.3 FAR-based Observations

None of the facility types nor the overall weighted average for all facilities had any discernible trend in FAR-based observations over the last three years. The results of the preliminary trend analysis of FAR-based observations are presented in *figure 3-27*.

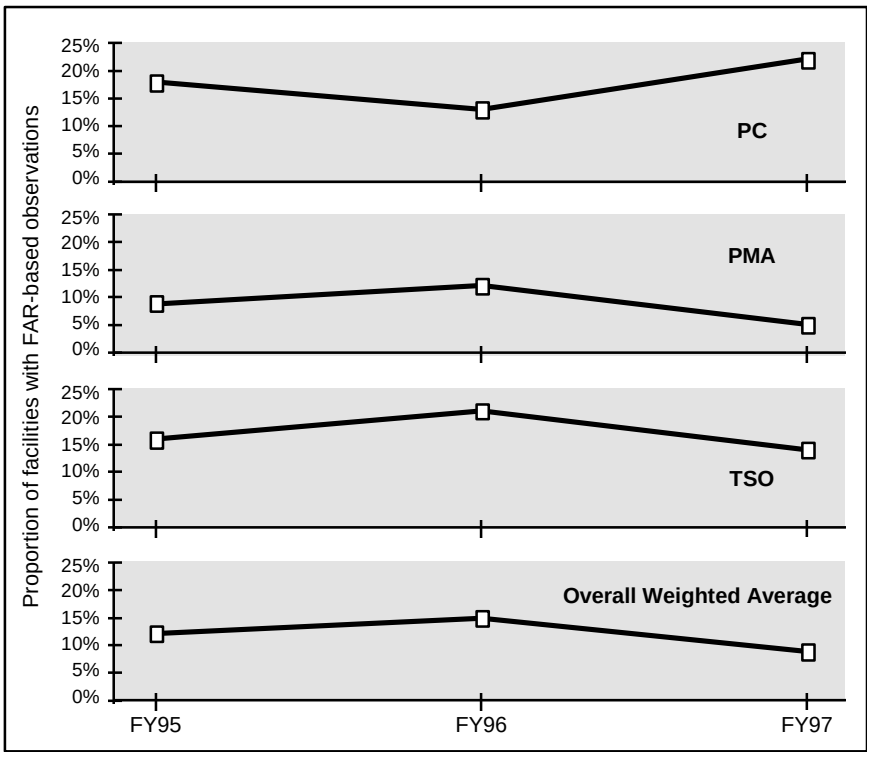

Figure 3-27.—Preliminary trend data for FAR-based observations.

3.7.4 Subsystem Trends for Systemic Issues

Preliminary trend analysis was performed on the systemic issues within the Manufacturing Process and Supplier Control subsystems. These two subsystems were chosen because they are the most prevalent issues among the various facility types and they have sufficient data in order to perform the analysis with reasonable reliability. As with the previous subchapters, the reader is cautioned that the results of these analyses are preliminary and reminded that further data is required before any defensible trends can been established.

Figure 3-28 depicts the trend data for the Manufacturing Process subsystem. None of the facility types nor the overall weighted average for all facilities had any discernible trend in the occurrence of systemic manufacturing process issues except for the biannual cyclical fluctuation in the PC holder data noted earlier.

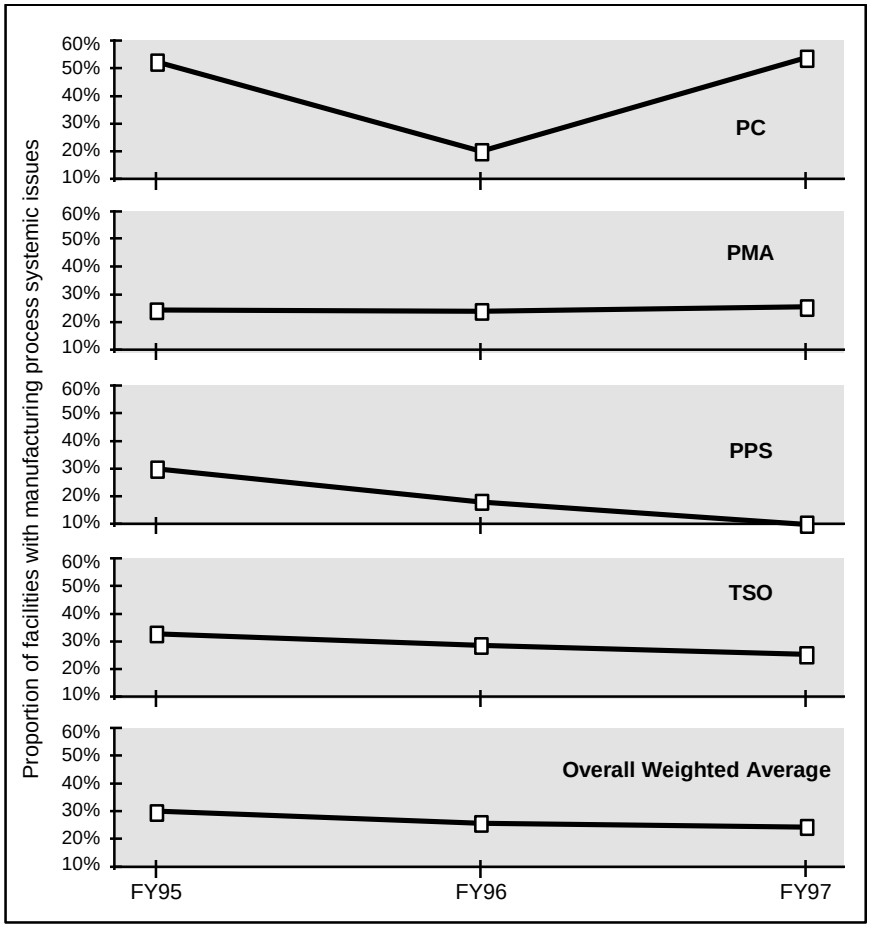

Figure 3-28.—Preliminary trend data for systemic manufacturing process issues.

Figure 3-29 depicts the trend data for the Supplier Control subsystem. The results are similar to those for the Manufacturing Process subsystem.

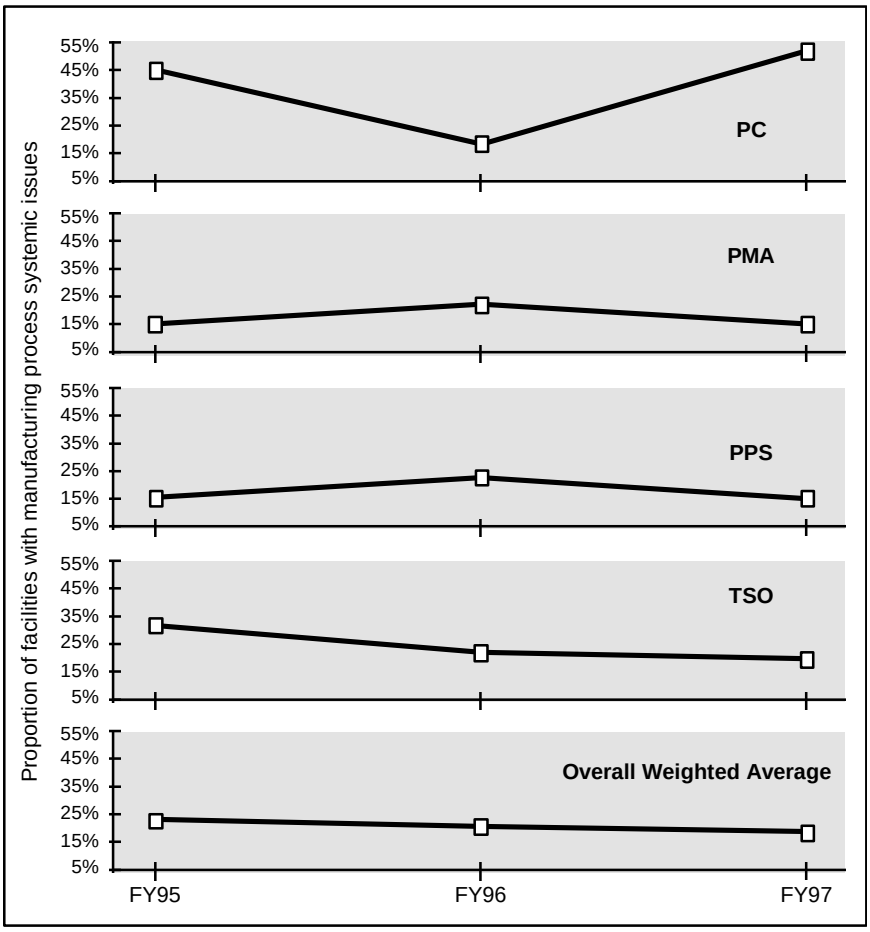

Figure 3-29.—Preliminary trend data for systemic supplier control issues.

3.8 Internal Audit

Building on an analysis introduced in the FY 1996 report, a correlation analysis was performed on the differences between the level of and incidence of systemic issues for those facilities with and without an effective internal audit program. The first part of the analysis compared the probability of systemic issues occurring at facilities with effective and ineffective internal audit programs. The second part of the analysis focused on the number of issues there were at the two groups of facilities.

The null hypothesis investigated for the first half of the analysis is that the probability of a facility having systemic issues in areas other than internal audit is independent from a facility having an effective internal audit program. The alternative hypothesis is that a facility with an ineffective internal audit program has a higher probability of systemic issues in areas other than internal audit.

The following definitions were used:

Effective audit program	–	The facility had implemented an internal audit program as described in Order 8100.7 (criteria 15M1) and had not received findings nor systemic observations in the Internal Audit subsystem. It should be noted that no qualitative assessment of the internal audit program was made by the FAA. Any facility with an internal audit program, as defined in Order 8100.7, that was found to be in compliance with its own procedures and policies was deemed to have an effective internal audit program for the purposes of analysis only.
Ineffective internal audit program	–	Those facilities where criteria 15M1 was in place, but had findings or systemic observations issued for either criteria 15M1 or criteria 15M2.
No internal audit program	–	Facilities where criteria 15M1 was rated as either "4" or "6", i.e., not in place or not applicable. *Facilities where the Internal Audit subsystem had not been evaluated, i.e., those rated with a "5", were not included in the analysis as their internal audit status could not be ascertained. Any facility that received a finding or systemic observation in criteria 15M1 because the documented internal audit program had not yet been implemented or had not been used for several years was also excluded from the analysis.*

Several analysis methods were used in order to verify the results: chi-squared contingency tables, confidence intervals (as seen in the figures), and pooled Z-tests for significance. All tests supported the null hypothesis; i.e., a facility with systemic issues in its internal audit program has a higher probability (at least 29 percent higher) of having systemic issues in subsystems other than internal audit than a facility having an internal audit program that does not have any systemic issues. As *figure 3-30* illustrates, the relationship between a facility not following its documented internal audit procedures and the probability of systemic issues is extremely strong (the analysis has a p-value of less than 2.6×10^{-8}). In fact, virtually all of the facilities having systemic issues with their internal audit programs also had systemic issues in other areas.

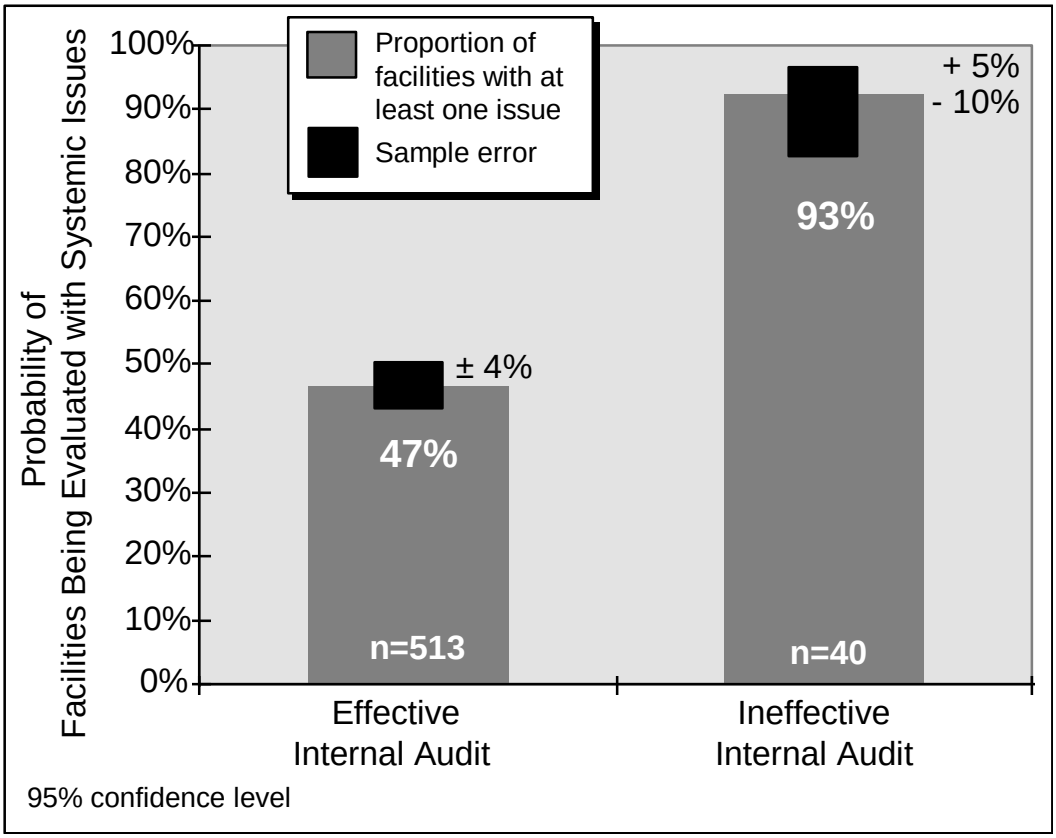

Figure 3-30.—Comparison of systemic issues for facilities with effective and ineffective internal audit programs.

The second part of the analysis focused on whether ineffective internal audit programs increase the number of findings and systemic observations. The null hypothesis investigated whether the number of systemic issues in areas other than internal audit is independent from a facility having an effective internal audit program. The alternative hypothesis was that facilities with ineffective internal audit programs have more systemic issues in areas other than internal audit.

The definitions for effective and ineffective internal audit given previously were used. As in the previous analysis, several statistical tests[13] were performed in order to confirm the findings. The analysis clearly indicated an increase in the number of findings and systemic observations for facilities with ineffective internal audit over those with effective internal audit. A p-value of less than 2.3×10^{-11} was obtained from the analysis of all facilities, *see figure 3-31*, and a p-value of .006 was obtained from the analysis of only those facilities with at least one systemic issue other than within the internal audit subsystem, *see figure 3-32*. The comparison of the respective frequency distributions is shown in *figure 3-33*. With this relationship established, it is appropriate to view the average number of systemic issues for facilities with ineffective internal audit programs as significantly higher than for those facilities with effective internal audit programs.

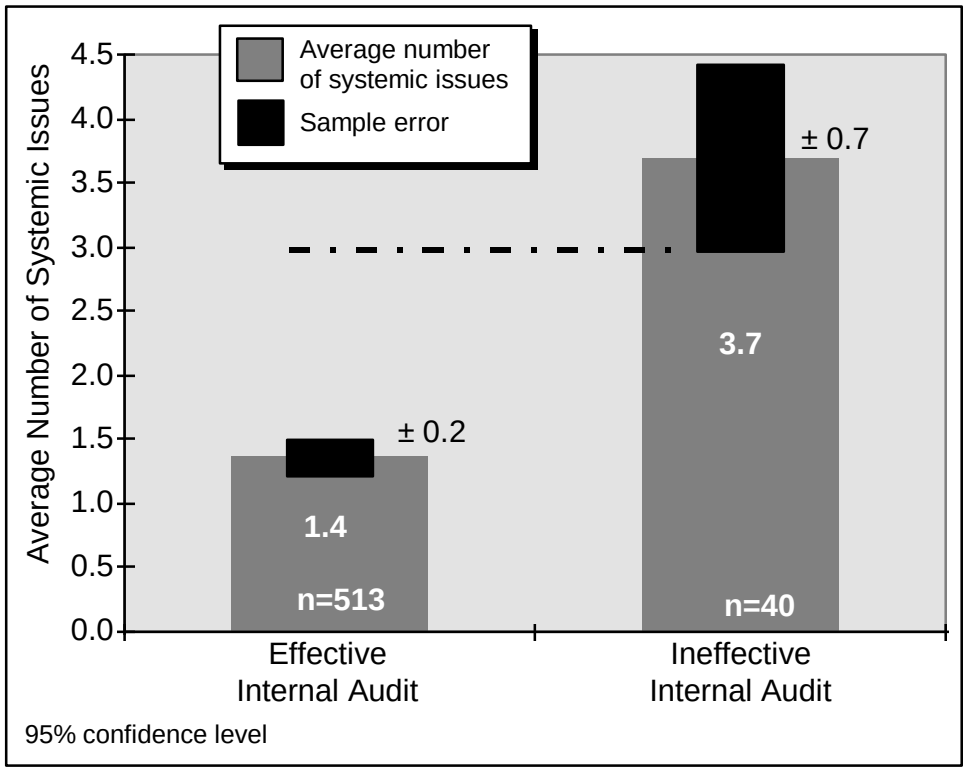

Figure 3-31.—Comparison of the number of systemic issues at facilities with effective and ineffective internal audit programs (all facilities).

[13] In order to maintain analysis reliability of the chi-squared analysis, the systemic issues were divided into five levels: one, two, three, four or five, and six or more systemic issues. The mean and standard deviation of the actual number of issues other than within the Internal Audit subsystem were used for the Z-test and confidence intervals.

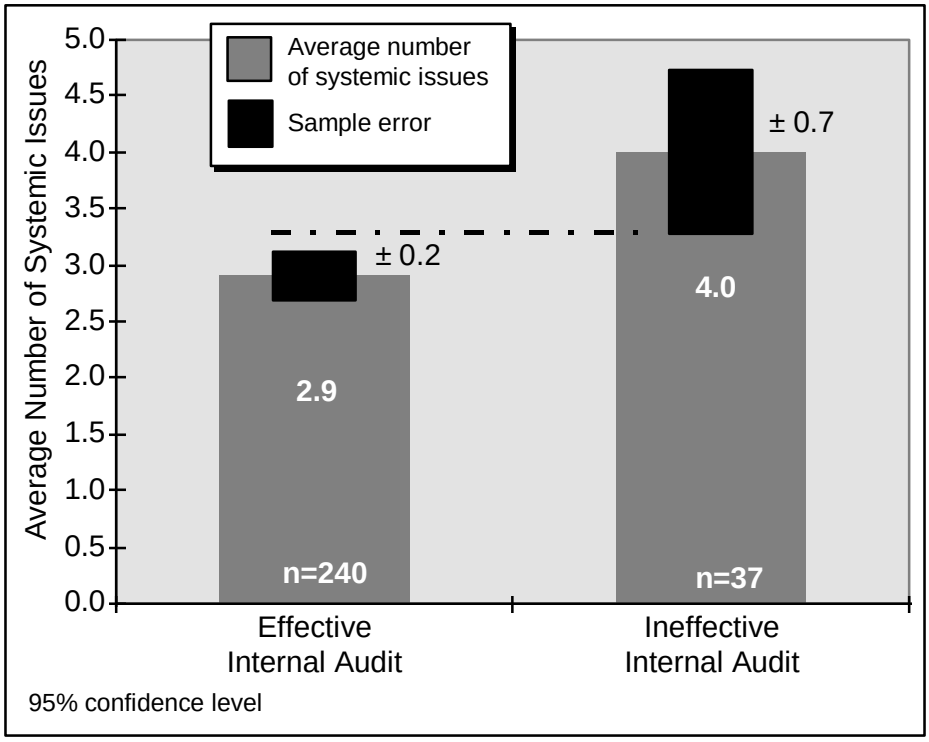

Figure 3-32.—Comparison of the number of systemic issues at facilities with effective and ineffective internal audit programs (facilities with at least one systemic issue in other than the internal audit subsystem).

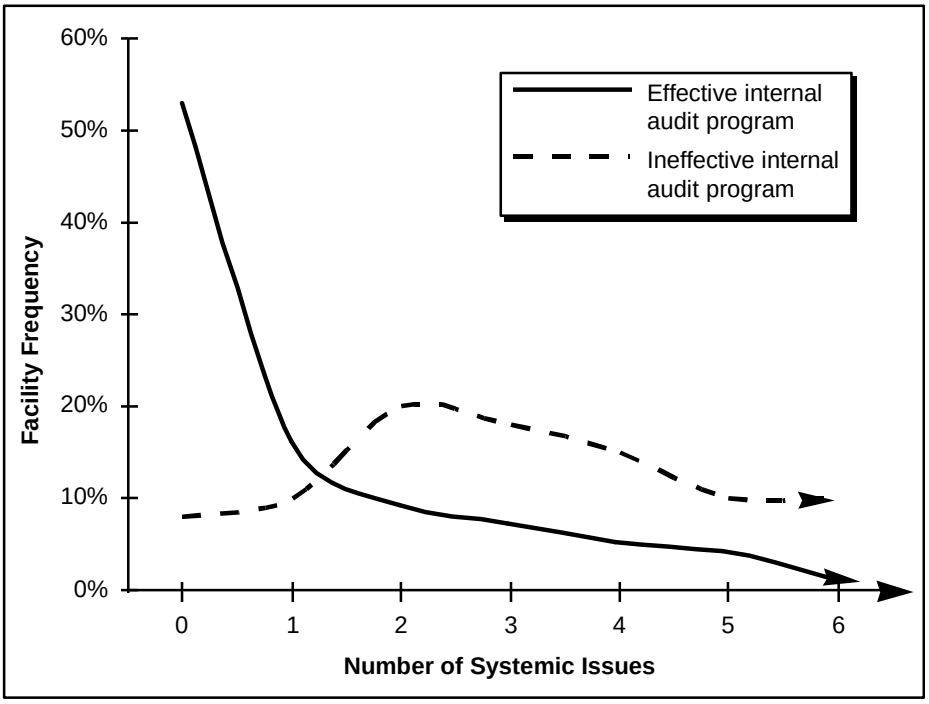

Figure 3-33.—Partial frequency distribution of facilities with systemic issues other than within the internal audit subsystem.

An analysis comparing the probability and quantity of systemic issues at facilities with and without internal audit programs could not be accomplished with sufficient reliability. The current ACSEP evaluation database does not record the level nor the depth of implementation of internal audit programs. No distinction is made, for example, between a facility utilizing only statistical sampling on a small portion of their processes and that of a facility with a fully deployed, root-cause corrective action internal audit program with regular status reviews by upper management. Without a measure of the depth and breadth of deployment, and thereby no means to qualify the internal audit systems, it is not possible to make assertions as to the effectiveness of those internal audit programs in reducing systemic issues.

Notwithstanding this limitation, this year's analysis has yielded a significantly better understanding of the effect internal audit has on general procedural compliance. A facility with systemic issues within its internal audit system is twice as likely to have additional systemic issues as a facility with an effective internal audit system. Internal audit is a tool that a facility's management can use to monitor and control its own processes. The data indicates that systemic issues within the critical area of internal audit can cause loss of quality system control within the areas that internal audit is attempting to monitor. In fact, facilities with discrepant internal audit systems had on average two more findings than those facilities whose internal audit systems were compliant with their own policies and procedures. These results should be carefully considered by both industry and the FAA when addressing facilities with internal audit programs that are not in compliance with stated procedures and policies.

3.9 Analysis of International Facilities

There were 44 ACSEP evaluations performed at international facilities. The distribution by facility type of these evaluations is as follows:

Facility Type	Number of ACSEP Evaluations
Production Certificate Extensions (PCEX)	1
Priority Part Suppliers (PPS)	43

The distribution of systemic issues for the international facilities, as shown in *figure 3-34*, is similar to that of domestic facilities (refer to *figure 3-17*). The ranking of issues among the various subsystems is very similar between domestic and international facilities. The rate of occurrence of issues appears higher at international facilities; however, this could be due to the low sample size not being representative of the whole population of facilities. Further analysis is not possible at this time due to the low volume of available data.

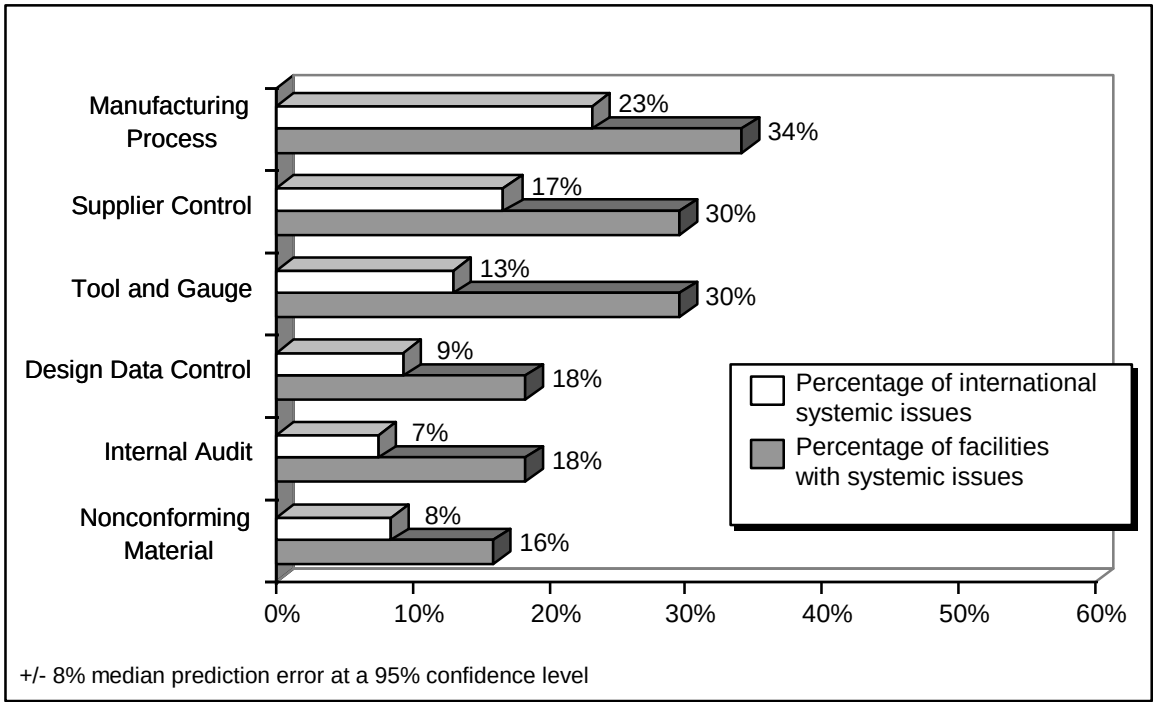

Figure 3-34.—Systemic issues – international facilities.

3.10 Significant Achievements during the Fiscal Year

Two events worthy of special note occurred during fiscal year 1997. The first was a result of issues uncovered during an ACSEP evaluation, and the second was a result of meetings with the industry groups Aerospace Industries Association (AIA) and the General Aviation Manufacturers Association (GAMA).

At two separate ACSEP evaluations, a concern was noted that the National Institute of Standards and Technology (NIST) had ceased production in 1994 of Standard Reference Material (SRM) 1001 X-ray Step Tablets for use in radiographic nondestructive inspection. With a defined stable shelf life of four years, the lack of step tablets with calibration traceable to NIST would become a critical issue for the aviation industry by early 1998. The Production & Airworthiness Certification Division sent a letter to NIST in mid-March 1997 expressing its concern in the matter. Based upon the concerns of the FAA as a regulatory agency, NIST was able to solidify its decision on how to best address the issue of maintaining standards and to prioritize the development of a new production method for the step tablets. As a result, NIST had begun shipping replacement step tablets prior to the end of the year.

The second significant event occurred at the October 1997 meeting of the Manufacturing, Maintenance, Repair Committee (MMRC) of AIA/GAMA. After an exchange of ideas on how ACSEP could better serve the aviation community, the MMRC accepted a proposal made by the FAA to form a committee to discuss the future collaborative development of analysis methods and models that could better serve both the FAA and industry. This committee will meet with the FAA in the fourth quarter of FY1998 to discuss the preliminary results of the FY 1998 ACSEP data and formulate theories as to what may be causing the trends. The joint FAA and industry team will then formulate a plan of action to verify these theories as a precursor to developing solutions to any discovered underlying issues that are causing the observed trends. In this manner, ACSEP will evolve with the industry and provide a tool to proactively develop plans to ensure continued operational safety.

4. Improvement Emphasis

The goal of the ACSEP is to support continuing operational safety and promote continuous improvement.

4.1 Industry Feedback

As part of the ACSEP Quality Improvement Program, a performance feedback report (FAA ACSEP Evaluation Feedback Report) is provided to each evaluated organization when notified that an evaluation is scheduled to take place. Each facility evaluated is requested to use this report to critique the FAA ACSEP evaluation process. The feedback report is used to record the facility's impression for each step of the evaluation, from notification to the post-evaluation conference. A question concerning the professionalism of the ACSEP evaluation team is also included on the report. The facility's management is encouraged to complete the report and return it for analysis. Feedback reports were returned by 56 percent of the facilities, up from 43 percent the previous year.

Overall, the feedback received was very good. Greater than 99 percent of the responses were "satisfactory" or better (See *figure 4-1*). For the third year, the area with the lowest score and with the most "poor" marks was pre-evaluation arrangements (the initial notification and subsequent discussions and plans up to the time of the evaluation). The two reasons most frequently given for these lower scores were: (1) the notification was not timely, and (2) the information provided was insufficient for the facilities to properly prepare to assist the evaluation. (The number of team members was unknown or different from what the notification letter indicated). The FY 1997 feedback is consistent with that of FY 1996 and FY 1995 and slightly more favorable. *Figure 4-2* gives the average scores for each of the six feedback categories measured and an overall average.

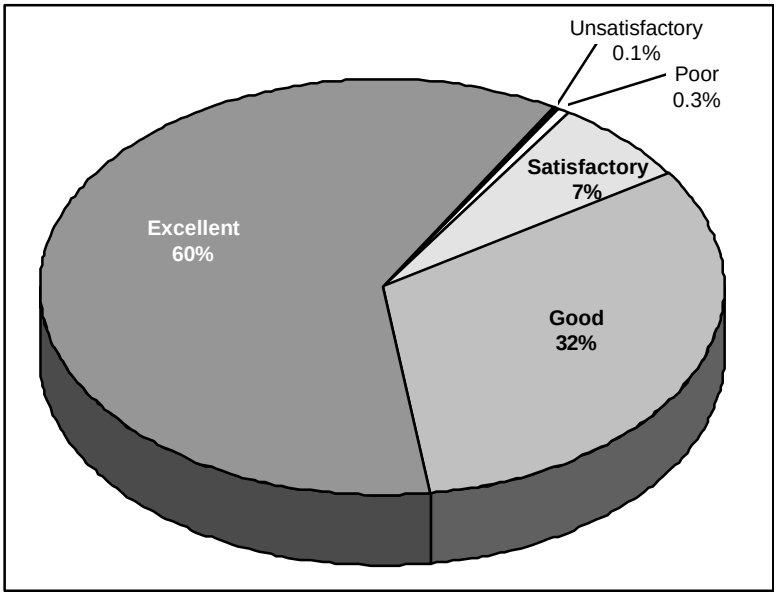

Figure 4-1.—Distribution of industry feedback.

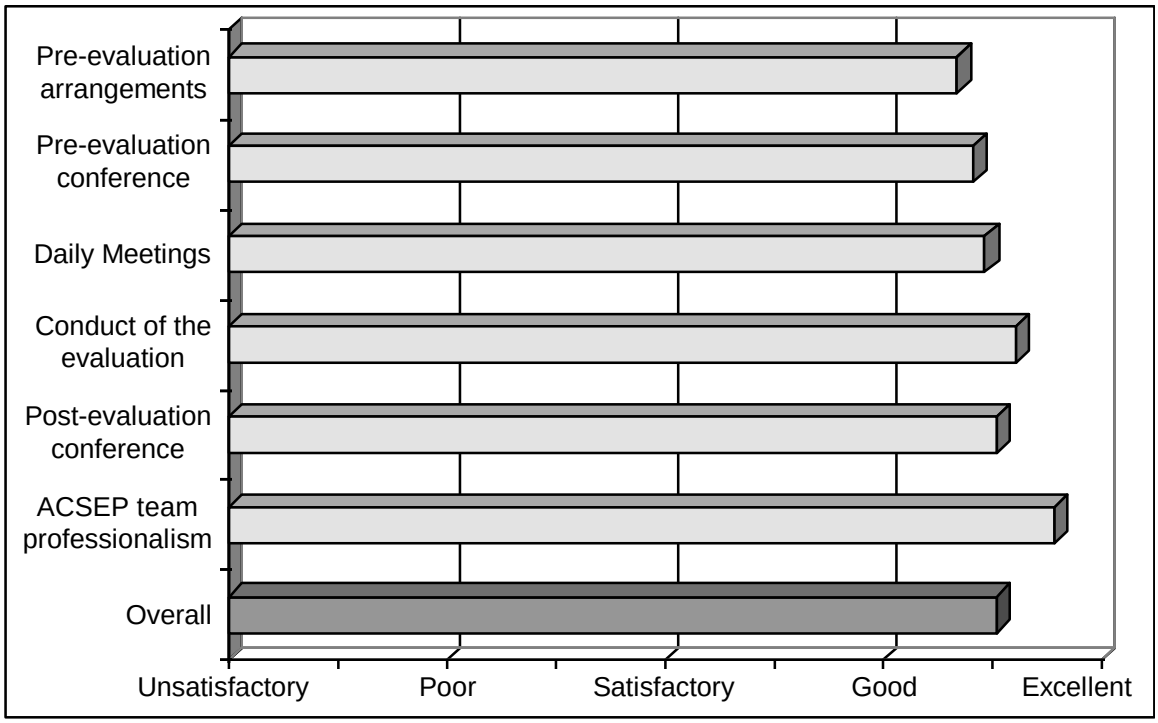

Figure 4-2.—ACSEP as graded by industry.

4.2 Lessons Learned

An additional part of the continuous improvement process is the gathering and analyzing of lessons learned that the evaluation team documented at the conclusion of each ACSEP evaluation. Each ACSEP evaluation team submits a "lessons learned" form that records the team's general assessment of the evaluation, difficulties with the order, subsystems not evaluated, and any proposed new criteria. *Figure 4-3* shows the trend in these lessons learned from FY 1994 to FY 1997.

Only five percent of the teams had problems using Order 8100.7 to conduct the evaluations, a five percent improvement over the previous year. Less than one percent of the evaluation teams required the use of new criteria not already contained in the order. There was a slight increase in the percentage of teams reporting general issues and difficulty. This increase in issues can be attributed to the increase in the number of evaluations at international facilities. Analysis shows that issues and/or difficulties are twice as likely to occur during the evaluation of international facilities as during the evaluation of domestic facilities (See *figure 4-4*). The most often cited issue was the presence of a language barrier, either in communicating with the facility escorts or in the lack of manuals and procedures written in English. The second most often cited cause of difficulty was the presence of cultural differences between the evaluation team and the personnel/management at international facilities. In most of the reported cases of cultural differences causing an issue, adjustments were made by either the evaluation team or the facility personnel to accommodate the cultural diversity.

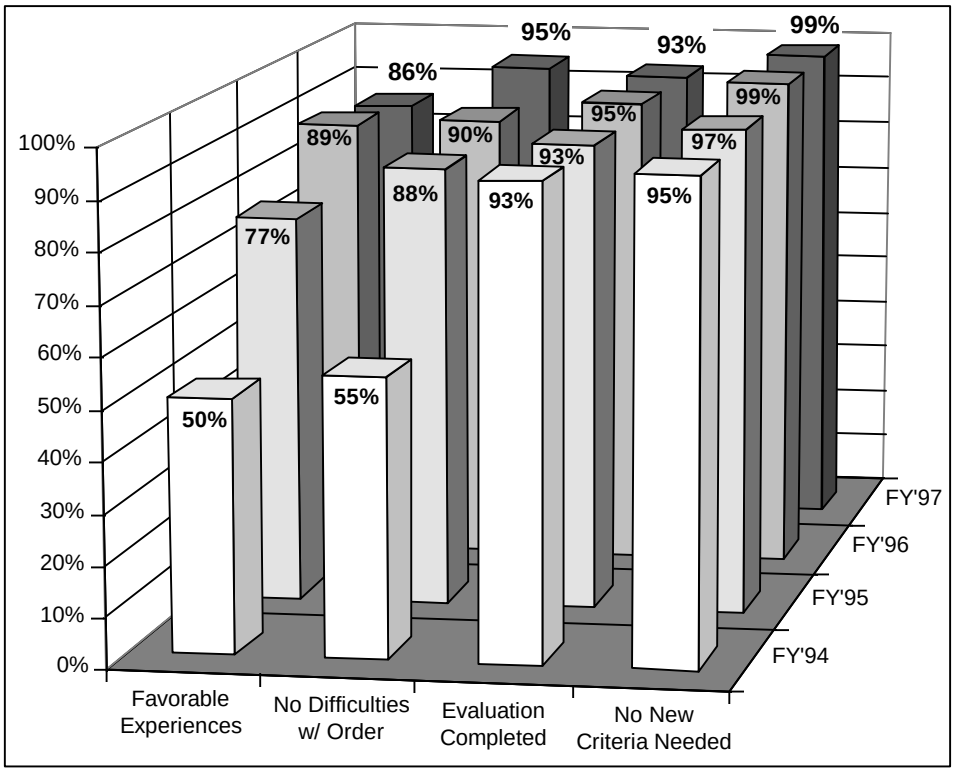

Figure 4-3.—Lessons learned trend.

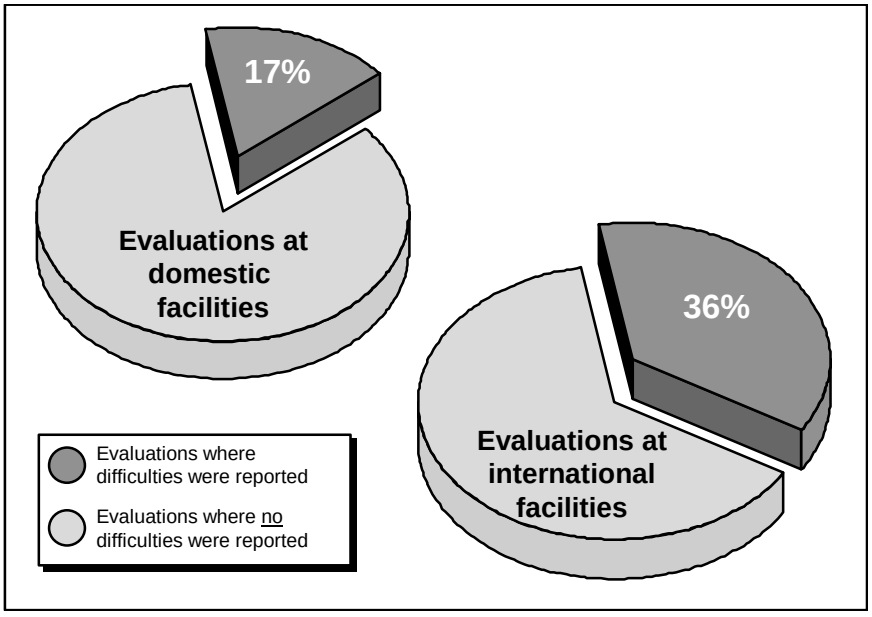

Figure 4-4. —Lessons learned – ACSEP evaluations at domestic vs. international facilities.

Although only seven percent of the evaluations were not completed in FY 1997 (*figure 4-3* — 93% of evaluations were completed), analysis of the specific subsystems not evaluated (see *figure 4-5*) presents a concern with the process team leaders used to select which applicable subsystems to evaluate. *Figure 4-5* indicates that many of the subsystems not evaluated are also subsystems identified as frequent issues in *Section 3.5*.

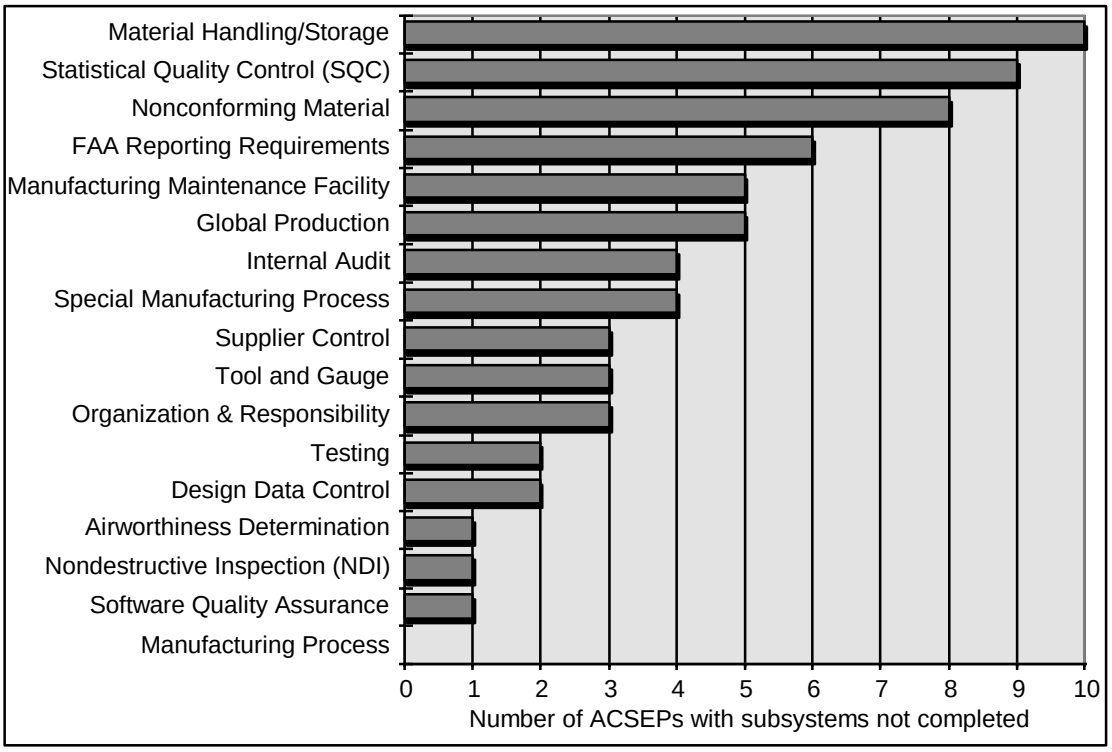

Figure 4-5.—Distribution of subsystems not evaluated.

There is a significant risk of missing systemic issues if these subsystems with a higher probability of having issues are not evaluated. Based on this new information, team leaders, as a minimum, should ensure that the prevalent subsystems identified in *Section 3.5* are always evaluated in future evaluations. For example, *figures 3-11 through 3-16* show the control of nonconforming material as one of the more prevalent issues, and the third most prevalent issue for PMA holders; however, evaluation of the control of Nonconforming Material subsystem was among the top three subsystems not completed. The team leader of an evaluation should not consider deferring an evaluation of any of the most prevalent issues unless there are very strong extenuating circumstances. This issue will be stressed in future training programs.

See *Table 4-1* for a list of other comments received with the lessons learned.

TABLE *4-1.—Comments received from lessons learned sheets*

Critical Comments	**FY'94**	**FY'95**	**FY'96**	**FY'97**
Time scheduled at facility was too short or too long	8%	5%	6%	5%
QC Manual incomplete, outdated, conflicts with other procedures	3%	3%	1%	1%
Production is very low, inactive, or inappropriate for audit	n/a	7%	2%	1%
Computers or ACSEP software issues	2%	3%	0%	0%
Difficult to establish FAA-authorized data for TSO authorizations	n/a	1%	0%	0%
Logistics; no escorts or QC mgr., facility not notified	3%	2%	0%	2%
Language barriers	n/a	1%	0%	1%
Misc. other issues	3%	2%	2%	2%
Difficulty with Order	**FY'94**	**FY'95**	**FY'96**	**FY'97**
Criteria; add, incorrect, or subsystem issues	8%	6%	5%	4%
Observations & findings; confusion with definitions	2%	1%	1%	0%
Confusion with the application of 4's and 6's on Form 8100-4[14]	2%	1%	1%	0%
Redundant criteria	n/a	1%	0%	0%
Confusion about recording multiple occurrences of findings or observations	n/a	1%	1%	1%
ACSEP too comprehensive for facility	1%	2%	2%	0%
Flow chart in Appendix 8 is difficult to use[15]	n/a	n/a	1%	0%
Other Comments	**FY'94**	**FY'95**	**FY'96**	**FY'97**
ISO 9000 certification better prepared the facilities for ACSEP evaluation	n/a	1%	1%	1%
Recommend extending evaluation frequency	2%	1%	1%	1%

[14] As per Appendix 8 in Order 8100.7, a "4" is used to specify "criteria not in use" and a "6" is used to specify "not applicable."

[15] The flow chart is figure 1.—*Rating of subsystem evaluation criteria* presented in Appendix 8, *Preparation instructions for FAA Form 8100-4, ACSEP rating sheet* of Order 8100.7, Aircraft Certification Systems Evaluation Program.

Additionally, the decision of when to evaluate or not evaluate internal audit should be carefully considered in light of the conclusions presented in *Section 3.8* concerning internal audit. This analysis has shown that an internal audit system not in compliance with a facility's own procedures and policies is a strong predictor of additional systemic issues elsewhere within the facility. By performing an evaluation on the internal audit subsystem, the team leader will be provided with an invaluable insight into the general compliance of the facility and an indication as to the depth at which issues may permeate the facility, i.e., there is the possibility that the discovery of what may appear on the surface to be isolated issues could in reality be systemic in nature. However, team leaders are cautioned, once finding an internal audit system not in compliance, against focusing the evaluation with the purpose of accumulating findings and observations simply because their internal audit system was discrepant. Rather, the team leader should use this knowledge to gauge how deeply to investigate an isolated incidence of noncompliance to ensure it is not really a systemic issue. Because the Internal Audit subsystem is such a strong indicator of overall facility compliance, the maximum benefit from evaluating an internal audit system can be obtained if it is done early in the evaluation to afford enough time to use this information.

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APPENDIX A
HISTORY AND BACKGROUND OF ACSEP

A1. Background

The ACSEP was developed as a result of numerous years of experience with Quality Assurance Systems Analysis Review (QASAR) audits and observations made during an interim audit program called "Operation SNAPSHOT." Maintaining consistency with new FAA policies and regulations, with regards to the certificate management process, was also a consideration for the establishment of ACSEP. The intent was to establish a surveillance system that would meet the needs and requirements of the FAA and industry, while incorporating standardized evaluation practices and techniques consistent with the aircraft manufacturing environment and internationally recognized guidelines. The evaluation criteria were developed, in part, in conjunction with the Aerospace Industries Association and General Aviation Manufacturer's Association. By design, ACSEP will support continued operational safety in an ever changing aircraft manufacturing environment (e.g., new technologies, automation, and co-production) through recurring evaluations of facilities' quality management systems and tracking and trending areas for improvement.

A2. Overview

ACSEP is an Aircraft Certification Service program. The Production & Airworthiness Certification Division, AIR-200, is the national focal point for the reporting of ACSEP evaluation results. Order 8100.7 and Notice N8100.13 provide guidance and assign responsibility for the implementation of the ACSEP and are vital tools in assurance of the FAA's mission of continued operational safety. The program assesses the compliance of PAHs and delegated facilities to the requirements of applicable FAR and FAA-approved data, including compliance to the procedures established to meet those requirements. It also surveys the application of standardized evaluation criteria not required by the FAR to identify national trends that may require development of new or revised regulations, policy, and guidance.

Evaluation criteria are divided into six major systems and vary in proportion from a high side of 119 evaluation criteria or 53 percent of the total for the Quality System to a low side of 12 evaluation criteria or 5 percent for the Management System (reference *figure A-1*).

The six major systems are:

- Management
- Engineering
- Manufacturing
- Quality
- Service/Product Support
- Communication with the FAA

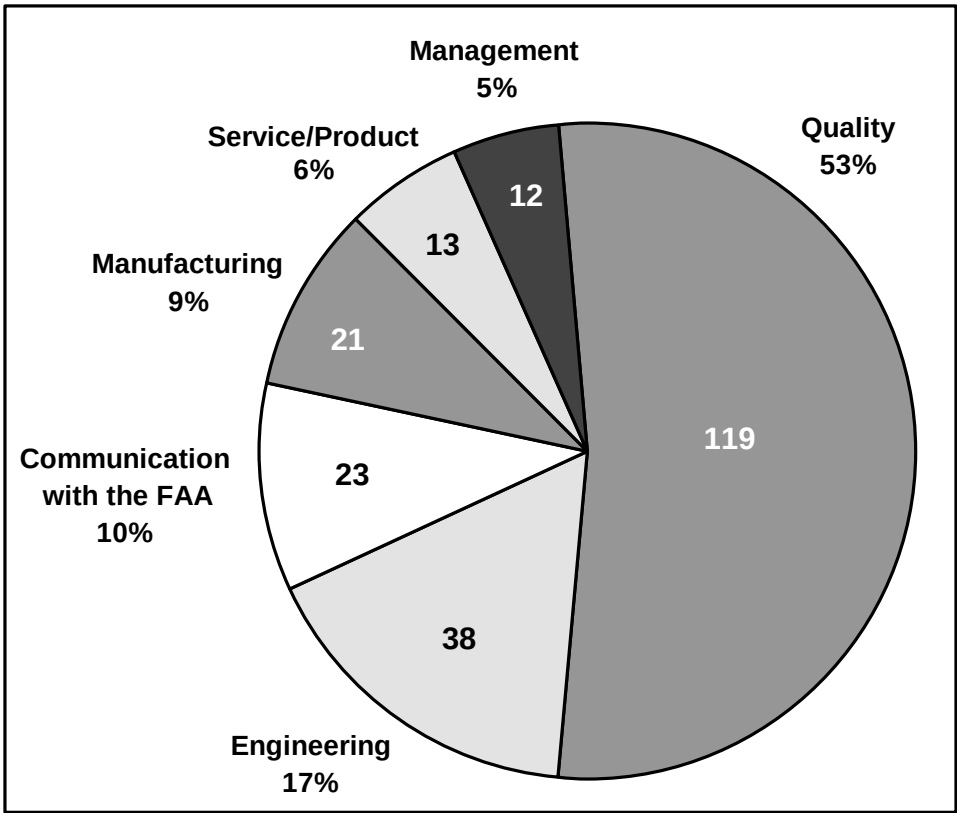

Figure A- 1.—Evaluation criteria distribution within the six major system elements of ACSEP.

The six system elements are further broken down into 17 subsystems for detailed data collection and reporting. The 17 subsystems are:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAR Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

Each of the 17 subsystems contains criteria that assess compliance to the various requirements of the FAR, FAA-approved data, and implementation of accepted industry practices. In total there are 226 evaluation criteria in ACSEP. However, the number of evaluation criteria contained in these systems and subsystems varies and is not equally proportioned to each facility type. The amount of variation is due to the FAR

requirements and industry practices for the different facility types. The 17 subsystems vary in proportion from a high side of 26 evaluation criteria or 12 percent of the total for Manufacturing Processes to a low side of two evaluation criteria or 1 percent for Internal Audit (reference *figure A-2*).

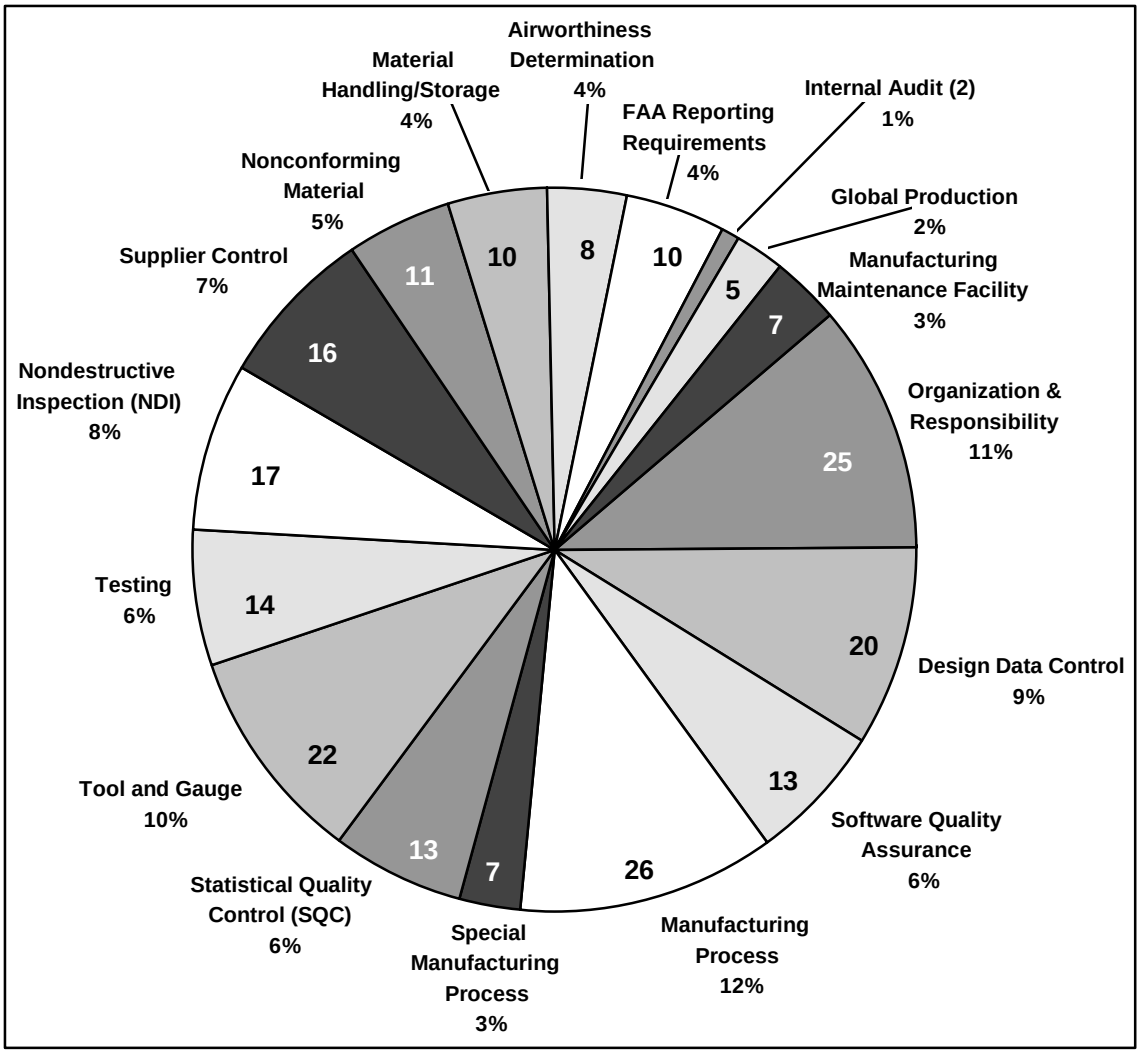

Figure A- 2. —Evaluation criteria distribution within the 17 subsystems of ACSEP.

A3. Evaluations and Evaluators

The ACSEP utilizes teams of FAA engineering, flight test, and manufacturing inspection personnel to evaluate PAHs, their priority part suppliers, and delegated facilities. Upon completion of each ACSEP evaluation, the team leader prepares a report and forwards it to the Certificate Management Office (Manufacturing Inspection Office or Aircraft Certification Office as applicable) which provides it to the Aviation Safety Inspector (ASI) and/or the Assigned Engineer (AE) responsible for the evaluated facility. A copy of the

report is also provided to AIR-200 for entry into the ACSEP database. The ACSEP database contains administrative information on facilities evaluated, status of qualified team members and team leaders, responses to rating criteria contained in the 17 evaluation subsystems, along with findings and observations noted. Additionally, the ACSEP Master Schedule, which is prepared annually, is maintained by AIR-200 together with the Directorate coordinators. The scheduling database is updated and posted to a Service wide electronic mail bulletin board on a monthly basis ensuring the Aircraft Certification Service offices are kept current of ACSEP evaluation cancellations, date changes, and recent additions.

The AIR organization is responsible for conducting evaluator training. This is accomplished in association with the FAA Academy with AIR-200 providing instructors. These instructors are experienced national evaluation team leaders who bring real life experiences into the classroom. While one instructor presents the course materials, the other critiques the presentation/materials and notes comments from students. The critique and notes are reviewed and improvements incorporated facilitating a continuous improvement process. Additionally, issues found in the field are also integrated into the course making it even more comprehensive and continuously improving.

The facilities are categorized into two evaluation frequencies, 24 and 48 months. The 24-month frequency includes PAHs, delegated facilities, and priority parts suppliers. The 48-month frequency covers PMAs that produce non-priority parts. The evaluation frequency may be increased based on the type of PAH, system capability, evaluation results, and the guidelines in FAA Order 8100.7 and Notice N8100.13. Evaluation frequencies may also be shortened to the extent necessary to obtain confidence that the facility is complying with applicable FAR. These decisions are made by the directorates based upon facility performance.

At the conclusion of an ACSEP evaluation, a post-evaluation conference is held with the evaluated facility management, and any issues, findings, and/or observations are reviewed. Any findings that require formal corrective action are pursued by the ASI and/or AE responsible for facility surveillance. The ASI and/or AE informs the facility of the findings and requests corrective action though a Letter of Investigation, when deemed appropriate. Corrective action is tracked by the ASI and/or AE until closure on FAA Form 8100-5, Results of ACSEP Evaluation Findings.

The ACSEP also includes a Quality Improvement Program. Data from the evaluation feedback reports and evaluation reports are used to prompt improvements in the program. Suggestions, comments, and results of the evaluations are reviewed by continuous improvement teams established in each directorate and in the headquarters office. The directorate teams act upon improvements that can be implemented locally; improvements that affect the national program are referred to a dedicated National Continuous Improvement Team (NCIT) made up of FAA Aviation Safety Inspectors, Aerospace Engineers, and Flight Test Pilots representing the directorates and headquarters. Managers

representing the Aircraft Certification Management Team (ACMT), Aircraft Certification Office Management Team (ACOMT), and Manufacturing Inspection Management Team (MIMT) are also members of the NCIT. After a comprehensive review of the data, the NCIT then recommends changes or clarification to current policy. Recommended changes are forwarded to the Aircraft Engineering Division (AIR-100) or the Production & Airworthiness Certification Division (AIR-200) for further review and possible implementation.

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APPENDIX B
DEFINITIONS

Approved Production Inspection System (APIS) – Federal Aviation Administration (FAA) production approval issued to a manufacturer of an aircraft, aircraft engine, or propeller being manufactured under a type certificate only.

Assigned Engineer – An FAA engineer to whom the Aircraft Certification Office manager has assigned responsibility relating to ACSEP evaluations at a particular design approval facility.

Compliance – for the purposes of this report, compliance refers to a facility's business practices being consistent with published procedures and/or policies. These procedures/policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the FAR.

Compliance Rate – the proportion of facilities whose business practices were found to be in compliance with published procedures and/or policies at the time of an ACSEP evaluation. These procedures/policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the FAR.

Criteria – the basic element of an ACSEP evaluation. Criteria are used to plan the depth of the evaluation and to document the results of the evaluation in a standardized manner. The criteria are grouped into subsystems and systems.

Delegated Facility – a facility undertaking DOA, DAS, or SFAR-36 activity.

Delegation Option Authorization (DOA) – an organization or facility authorized by the FAA to accomplish type, production and airworthiness certification of certain products as specified in FAR § 21.231(a).

Designated Alteration Station (DAS) – an organization or facility authorized by the FAA to issue supplemental type certifications, experimental certificates, and amended standard airworthiness certificates in accordance with its FAA-approved procedures manual.

Established Industry Practice – a widely followed method of operating that achieves consistent performance of specific functions (i.e., calibration recall system, internal audit system, and statistical process control).

Facility – for this report, any production approval holder or priority part supplier.

FAR-based Observation – an occurrence of FAA-approved data not in compliance to a FAR.

Federal Aviation Regulations (FAR) – regulations listed in Title 14 (Aeronautics and Space) of the Code of Federal Regulations (CFR).

Finding – systemic noncompliance to the FAR, FAA-approved data (or in the case of supplier facilities, the purchasing instrument), or a safety-related noncompliance.

Issue – An inconsistency between the actual operating practices of a facility and the FAR, FAA-approved data, or the facility's internal procedures.

Isolated Observation – isolated occurrence of noncompliance to the FAR or FAA-approved data.

Manufacturer's Maintenance Facility (MMF) – defined by FAR § 145.1(c) as a repair station certificate with a limited rating issued to a manufacturer based upon the Production Approval they hold from the FAA.

National Continuous Improvement Team (NCIT) – a dedicated national team of FAA Aviation Safety Inspectors, Aerospace Engineers, Flight Test Pilots, and managers representing the Directorates and Divisions chartered to review the ACSEP periodically for areas of improvement.

Noncompliance – for the purposes of this report, noncompliance refers to a facility's business practices being inconsistent with published procedures and policies at the time of the ACSEP evaluation. These procedures and/or policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the FAR.

Noncompliance Rate – the proportion of facilities where at least one business practice was found not to agree with published procedures or policies, or any portion thereof, at the time of the ACSEP evaluation. These procedures and/or policies include: internal procedures not requiring FAA approval, FAA-approved data, and the FAR.

Parts Manufacturer Approval (PMA) – an FAA production and design approval issued to manufacturers who produce replacement or modification parts, equipment, components, materials, part processes (replacement and modification, and appliances.

Principal Inspector (PI) – an FAA Aviation Safety Inspector who has been assigned certificate management and/or surveillance responsibility for a PAH, associate facility, or PPS.

Priority Part Supplier (PPS) – any person or organization (including a distributor) the furnishes priority parts (as defined in Order 8120.2A) to a PAH.

Production Approval Holder (PAH) – the holder of a Production Certificate, APIS, PMA, or Technical Standard Order (TSO) authorization, who controls the design and quality of a product or part thereof.

Production Certificate (PC) – an FAA production approval issued to a manufacturer of aircraft, aircraft engines, or propellers that has had its Quality Control System examined and approved by the FAA, and that holds one or more of the following: a current type certificate; rights to the benefits of a type certificate under a licensing agreement; or a supplemental type certificate.

Production Certificate Extension (PCEX) – an FAA-approved extension of a specific manufacturer's PC to another facility.

Safety Finding – safety-related noncompliance that requires immediate action.

Special Federal Aviation Regulation No. 36 (SFAR-36) to FAR part 121 – an organization or facility authorized by the FAA to make major repairs on a product or article in accordance with its FAA-approved procedures manual.

Subsystem – a logical grouping of several criteria into functional areas. There are 17 subsystems within ACSEP.

System – the highest level of grouping for the ACSEP criteria. Systems comprise the individual disciplines under which the criteria fall. There are six systems: Management, Engineering, Manufacturing, Quality, Service/Product support, and Communication with the FAA.

Systemic Observation – systemic noncompliance to other than FAA requirements or FAA-approved data.

Technical Standard Order (TSO) a*uthorization*– an FAA design and production approval issued to a manufacturer for an article which has been found to meet a specific FAA Technical Standard Order.

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APPENDIX C
CRITERIA HAVING FINDINGS OR OBSERVATIONS

Tables C-1 through C-13 present data from only domestic facilities. The first three of these tables (*Tables C-1 to C-3*) presents the data for all facility types combined. The ten tables following (*Tables C-4 through C-13*) present the data for the particular facility type specified. *Tables C-14 and C-15* present the data from all of the international facilities. There is too little data to compare the two different facility types evaluated.

The column titled "Percent of Applicable Facilities with Issues" provides the frequency of findings and/or observations being reported at those facilities where the criteria was implemented. This column of data can be used to gauge the significance of the issues at those facilities where the capability for the criteria was implemented — a facility focus as described in *Subsection 3.6.2*. In contrast, the table column titled "Percent of Facilities" (percent of all domestic facilities for *Tables C-1 through C-3* or percent of the domestic facilities within a particular facility type for *Tables C-4 through C-13* or percent of all international facilities for *Tables C-14 and C-15*) presents the frequency of facilities evaluated that had the criteria reported. This column can be used to gauge the importance of the criteria as it affects the industry as a whole — as described in *Subsection 3.6.1*.

TABLE C- 1.—Systemic findings and observations

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	15M1	Internal auditing program	30	5%	7%	10%
2	10Q1	Initial & periodic evaluations of suppliers	30	5%	7%	9%
3	4P9	Completed product/part identification	29	5%	7%	7%
4	5Q3	Accord with process specifications	21	3%	5%	9%
5	4M1	Operation within production limitations	17	3%	4%	4%
6	11Q1	Control of nonconforming products	17	3%	4%	4%
7	10Q5	Flow down of technical & quality requirements	16	3%	4%	5%
8	10Q10	Receiving inspection	16	3%	4%	4%
9	4Q5	Inspection records	16	3%	4%	4%
10	4P4	Work instructions control manufacturing processes	15	2%	3%	4%
11	12Q3	Storage of conforming parts	15	2%	3%	4%
12	11Q2	Permanent identification of scrap material	14	2%	3%	4%
13	4Q1	Inspection methods and plans	14	2%	3%	4%
14	11Q4	Material review record generated	13	2%	3%	4%
15	10Q2	Use of approved suppliers	13	2%	3%	3%
16	7Q12	Calibration records	13	2%	3%	3%
17	12Q5	Identification of age control products	11	2%	3%	4%
18	7Q3	Tool & gauge recall system	11	2%	3%	3%
19	10Q8	Verification of raw material	11	2%	3%	3%
20	7Q1	Approval/inspection of tools & gauges	11	2%	3%	3%
21	4Q12	Completion of all inspections & tests	11	2%	3%	3%
22	2C1	Minor design change approval	9	1%	2%	3%
23	4E1	Accord with FAA-approved design data	9	1%	2%	2%
24	10Q6	Quality Assurance review of purchase documents	8	1%	2%	2%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
25	2E7	Design/Technical data document control	8	1%	2%	2%
26	1Q4	Quality Manual	8	1%	2%	2%
27	2C4	Data submittal for TSO minor changes	7	1%	2%	7%
28	7Q11	Control of production tooling	7	1%	2%	3%
29	4P5	Work instruction revision approval	7	1%	2%	2%
30	2E3	Technical data change approval	7	1%	2%	2%
31	5Q2	Required qualifications/approvals	6	1%	1%	3%
32	8E1	Test procedures/instructions established	6	1%	1%	2%
33	7Q6	Calibration & use in acceptable environment	6	1%	1%	2%
34	4P2	Work instructions prepared	6	1%	1%	2%
35	2E1	Design change approval	6	1%	1%	2%
36	9Q3	NDI procedures/specifications available & used	5	1%	1%	5%
37	5E1	All special processes in use identified	5	1%	1%	2%
38	8E2	Control of test procedure/instruction changes	5	1%	1%	2%
39	4P3	Work instructions reflect tech data	5	1%	1%	1%
40	7Q14	Identification of gauges	5	1%	1%	1%
41	2E2	Drawing control system	5	1%	1%	1%
42	10Q12	Records of receiving inspection	5	1%	1%	1%
43	1Q6	Record retention schedule	5	1%	1%	1%
44	6Q1	Statistical sampling inspection plans	4	1%	1%	2%
45	12Q2	Special environmental controls	4	1%	1%	2%
46	14C3	Submittal of quality system data changes	4	1%	1%	2%
47	2E8	Major/minor design changes	4	1%	1%	1%
48	4P1	Change approval	4	1%	1%	1%
49	7Q16	Inaccurate tools & gauges identified	4	1%	1%	1%
50	4P6	Familiarity with specifications	4	1%	1%	1%
51	2E9	Technical data file	4	1%	1%	1%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
52	3BE4	Software security	3	0.5%	1%	4%
53	9E2	Control of NDI processes & changes	3	0.5%	1%	3%
54	5Q4	Records maintained	3	0.5%	1%	1%
55	7Q9	Control of special processing equipment	3	0.5%	1%	1%
56	11E1	Engineering review for major/minor changes	3	0.5%	1%	1%
57	11Q6	Corrective action required	3	0.5%	1%	1%
58	4Q2	Location of inspection stations	3	0.5%	1%	1%
59	7Q2	Instructions for acceptance tooling	3	0.5%	1%	1%
60	7Q5	Accuracy of standards	3	0.5%	1%	1%
61	4Q3	Issuance of inspection stamps	3	0.5%	1%	1%
62	12Q1	Prevention of part damage/contamination	3	0.5%	1%	1%
63	7Q15	Care of tools & gauges	3	0.5%	1%	1%
64	2E6	Storage of design documents	3	0.5%	1%	1%
65	3AE1	Software Configuration Management Plan	2	0.3%	0.5%	4%
66	3BE2	Change documentation and approval	2	0.3%	0.5%	3%
67	9Q4	Tanks & solutions checked	2	0.3%	0.5%	2%
68	6Q10	Corrective action	2	0.3%	0.5%	2%
68	9Q1	Operator qualification	2	0.3%	0.5%	2%
69	10Q3	Approval of supplier quality manual	2	0.3%	0.5%	1%
70	13E1	AD incorporation	2	0.3%	0.5%	1%
71	8Q3	Records of completed tests	2	0.3%	0.5%	1%
72	4Q7	Control of environmental conditions	2	0.3%	0.5%	1%
73	11Q7	Corrective action monitored	2	0.3%	0.5%	1%
74	2C2	Major design change approval	2	0.3%	0.5%	1%
75	10Q9	Verification of shelf-life materials	2	0.3%	0.5%	1%
76	4Q6	Cleaners, solvents, etc., identified	2	0.3%	0.5%	1%
77	1M5	Policy document review	2	0.3%	0.5%	1%
78	12Q7	Control of product removal/issuance	2	0.3%	0.5%	1%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
79	4Q9	Traceability to raw material	2	0.3%	0.5%	1%
80	1M1	Overall policy document	2	0.3%	0.5%	1%
81	1Q5	Tags, forms, etc., described	2	0.3%	0.5%	1%
82	7P1	Appropriate measuring devices used	2	0.3%	0.5%	1%
83	7Q4	Traceability to national/international standards	2	0.3%	0.5%	1%
84	12Q4	Segregation of product in storage	2	0.3%	0.5%	0.5%
85	3AE6	Software development environment	1	0.2%	0.2%	2%
86	3AP1	Software identification	1	0.2%	0.2%	2%
86	3AQ1	Programmed media handling/storage	1	0.2%	0.2%	2%
87	17Q6	Completion of all requirements	1	0.2%	0.2%	2%
88	17Q2	Operation within certificate privileges	1	0.2%	0.2%	2%
88	17Q5	Record of completed work	1	0.2%	0.2%	2%
89	3BE3	Software problem reporting	1	0.2%	0.2%	1%
90	2C5	New TSOA for major design changes	1	0.2%	0.2%	1%
91	3BQ1	Verification prior to use	1	0.2%	0.2%	1%
92	9Q14	Critical penetrant parameters identified	1	0.2%	0.2%	1%
93	9E1	Engineering review of NDI processes	1	0.2%	0.2%	1%
94	9Q9	Records of compliance	1	0.2%	0.2%	1%
95	16Q5	Documents to importing country	1	0.2%	0.2%	1%
96	16Q3	Export airworthiness approvals obtained	1	0.2%	0.2%	1%
97	6E1	Engineering review of SQC techniques	1	0.2%	0.2%	1%
98	10Q4	Control of buyer-furnished material	1	0.2%	0.2%	1%
99	1E1	Engineering/Flight Test organizations described	1	0.2%	0.2%	1%
100	2S2	Distribution of Inst. for Continued Airworthiness changes	1	0.2%	0.2%	1%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
101	2E5	Changes to Instructions for Continued Airworthiness	1	0.2%	0.2%	1%
102	2E4	AD incorporation into design	1	0.2%	0.2%	0.5%
103	5Q1	Equipment available & calibrated	1	0.2%	0.2%	0.5%
104	7Q8	Use of personal gauges	1	0.2%	0.2%	0.4%
105	4P8	Traceability for split lots	1	0.2%	0.2%	0.4%
106	14S2	Record of service difficulties	1	0.2%	0.2%	0.4%
107	4P7	Identification/control of partially accepted parts	1	0.2%	0.2%	0.4%
108	1P3	Manufacturing staff qualifications	1	0.2%	0.2%	0.4%
109	7Q19	Tool & gauge rework/reinspection	1	0.2%	0.2%	0.4%
110	7Q13	Adjustment of calibration intervals	1	0.2%	0.2%	0.3%
111	1Q3	Quality Assurance staff qualifications	1	0.2%	0.2%	0.3%
112	11Q3	MRB established and operational	1	0.2%	0.2%	0.3%
113	11Q5	Reinspection/retest after rework/repair	1	0.2%	0.2%	0.3%
114	10Q7	Action on problem notification	1	0.2%	0.2%	0.3%
115	14C1	Failure reporting	1	0.2%	0.2%	0.3%
116	11M1	Management review of data	1	0.2%	0.2%	0.3%
117	4Q11	Inspection before closure	1	0.2%	0.2%	0.3%
118	2Q1	QA review of design/technical data changes	1	0.2%	0.2%	0.3%
119	1M2	Organizations described	1	0.2%	0.2%	0.3%
120	1Q2	Quality Assurance Manager identified	1	0.2%	0.2%	0.3%
120	1M6	Policies/procedures availability	1	0.2%	0.2%	0.3%
121	4Q10	Inspection marking	1	0.2%	0.2%	0.3%
122	12Q8	Conforming products packaged & shipped	1	0.2%	0.2%	0.3%
123	1Q1	Quality organizations described	1	0.2%	0.2%	0.3%
123	7Q7	Accuracy of inspection & test equipment	1	0.2%	0.2%	0.3%
		TOTAL	**640**			

TABLE C- 2.—Isolated observations

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	12	6%	3%	4%
2	11Q2	Permanent identification of scrap material	11	5%	3%	3%
3	12Q5	Identification of age control products	10	5%	2%	3%
4	11Q1	Control of nonconforming products	10	5%	2%	3%
5	15M1	Internal auditing program	9	4%	2%	3%
6	2E1	Design change approval	8	4%	2%	2%
7	7Q1	Approval/inspection of tools & gauges	8	4%	2%	2%
8	4P4	Work instructions control manufacturing processes	6	3%	1%	2%
9	2E2	Drawing control system	6	3%	1%	2%
10	10Q5	Flow down of technical & quality requirements	5	2%	1%	1%
11	7Q14	Identification of gauges	5	2%	1%	1%
12	4P9	Completed product/part identification	5	2%	1%	1%
13	4Q5	Inspection records	5	2%	1%	1%
14	7Q3	Tool & gauge recall system	4	2%	1%	1%
15	2E7	Design/Technical data document control	4	2%	1%	1%
15	4Q1	Inspection methods and plans	4	2%	1%	1%
16	12Q3	Storage of conforming parts	4	2%	1%	1%
17	5Q3	Accord with process specifications	3	1%	1%	1%
18	5Q4	Records maintained	3	1%	1%	1%
19	8E1	Test procedures/instructions established	3	1%	1%	1%
20	10Q9	Verification of shelf-life materials	3	1%	1%	1%
21	4Q3	Issuance of inspection stamps	3	1%	1%	1%
22	10Q2	Use of approved suppliers	3	1%	1%	1%
23	1Q4	Quality Manual	3	1%	1%	1%
24	2C4	Data submittal for TSO minor changes	2	1%	0.5%	2%
25	7Q10	Control of NDI Equipment	2	1%	0.5%	1%
26	6Q1	Statistical sampling inspection plans	2	1%	0.5%	1%

TABLE C- 2.—Isolated observations—Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
27	8Q1	QA review of test instructions	2	1%	0.5%	1%
28	11Q3	MRB established and operational	2	1%	0.5%	1%
29	11Q6	Corrective action required	2	1%	0.5%	1%
30	7Q6	Calibration & use in acceptable environment	2	1%	0.5%	1%
31	4P5	Work instruction revision approval	2	1%	0.5%	1%
32	4P3	Work instructions reflect tech data	2	1%	0.5%	1%
33	10Q8	Verification of raw material	2	1%	0.5%	1%
34	12Q1	Prevention of part damage/contamination	2	1%	0.5%	1%
35	1Q5	Tags, forms, etc., described	2	1%	0.5%	1%
36	7Q15	Care of tools & gauges	2	1%	0.5%	1%
37	10Q10	Receiving inspection	2	1%	0.5%	1%
38	4Q12	Completion of all inspections & tests	2	1%	0.5%	0.5%
39	8E3	Approved flight checkoff form	1	0.5%	0.2%	4%
40	13Q1	Log books	1	0.5%	0.2%	4%
41	3AE1	Software Configuration Management Plan	1	0.5%	0.2%	2%
41	3AE2	Configuration Index Document	1	0.5%	0.2%	2%
42	17Q3	Work in accordance with Part 43 requirements	1	0.5%	0.2%	2%
43	17Q5	Record of completed work	1	0.5%	0.2%	2%
44	9Q13	Critical magnetic particle parameters identified	1	0.5%	0.2%	1%
45	3BE1	Software Configuration Management Plan	1	0.5%	0.2%	1%
46	3BQ1	Verification prior to use	1	0.5%	0.2%	1%
47	9Q14	Critical penetrant parameters identified	1	0.5%	0.2%	1%
48	9E2	Control of NDI processes & changes	1	0.5%	0.2%	1%
49	6Q10	Corrective action	1	0.5%	0.2%	1%
50	9Q3	NDI procedures/specifications available & used	1	0.5%	0.2%	1%
50	9Q9	Records of compliance	1	0.5%	0.2%	1%
51	6P1	Manufacturing review of SQC techniques	1	0.5%	0.2%	1%
52	10Q3	Approval of supplier quality manual	1	0.5%	0.2%	1%

TABLE C- 2.—Isolated observations—Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
53	8Q3	Records of completed tests	1	0.5%	0.2%	1%
54	5Q2	Required qualifications/approvals	1	0.5%	0.2%	0.5%
55	5Q1	Equipment available & calibrated	1	0.5%	0.2%	0.5%
56	7Q18	Action on product measured by SOT gauge	1	0.5%	0.2%	0.5%
57	1M4	FAA designee authority	1	0.5%	0.2%	0.4%
58	4Q7	Control of environmental conditions	1	0.5%	0.2%	0.4%
59	5E1	All special processes in use identified	1	0.5%	0.2%	0.4%
60	10E1	Control of supplier design and changes	1	0.5%	0.2%	0.4%
61	4P7	Identification/control of partially accepted parts	1	0.5%	0.2%	0.4%
62	14C3	Submittal of quality system data changes	1	0.5%	0.2%	0.4%
63	8E2	Control of test procedure/instruction changes	1	0.5%	0.2%	0.4%
64	15M2	Feedback to higher-level management	1	0.5%	0.2%	0.4%
65	4E2	New/changed process test substantiation	1	0.5%	0.2%	0.4%
66	7Q13	Adjustment of calibration intervals	1	0.5%	0.2%	0.3%
67	2C2	Major design change approval	1	0.5%	0.2%	0.3%
68	10Q7	Action on problem notification	1	0.5%	0.2%	0.3%
69	2C1	Minor design change approval	1	0.5%	0.2%	0.3%
70	7Q16	Inaccurate tools & gauges identified	1	0.5%	0.2%	0.3%
71	4P2	Work instructions prepared	1	0.5%	0.2%	0.3%
72	4Q10	Inspection marking	1	0.5%	0.2%	0.3%
73	7Q7	Accuracy of inspection & test equipment	1	0.5%	0.2%	0.3%
74	2E9	Technical data file	1	0.5%	0.2%	0.3%
75	7Q4	Traceability to national/international standards	1	0.5%	0.2%	0.3%
76	7Q12	Calibration records	1	0.5%	0.2%	0.3%
77	12Q4	Segregation of product in storage	1	0.5%	0.2%	0.2%
78	4E1	Accord with FAA-approved design data	1	0.5%	0.2%	0.2%
		TOTAL	**209**			

TABLE C- 3.—FAR-based observations

Rank	Criteria	Description	Number of FAR-based Observations	Percent of Total FAR-based Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4Q2	Location of inspection stations	4	10%	1%	1%
2	2C1	Minor design change approval	3	8%	1%	1%
3	1Q6	Record retention schedule	3	8%	1%	1%
4	2C5	New TSOA for major design changes	2	5%	0.5%	2%
5	5E1	All special processes in use identified	2	5%	0.5%	1%
6	2E8	Major/minor design changes	2	5%	0.5%	1%
7	10Q8	Verification of raw material	2	5%	0.5%	1%
8	4M1	Operation within production limitations	2	5%	0.5%	1%
9	1Q1	Quality organizations described	2	5%	0.5%	1%
10	4P9	Completed product/part identification	2	5%	0.5%	0.5%
11	8E3	Approved flight check off form	1	3%	0.2%	4%
12	17Q6	Completion of all requirements	1	3%	0.2%	2%
13	2C4	Data submittal for TSO minor changes	1	3%	0.2%	1%
14	9Q8	Acceptance/rejection criteria provided	1	3%	0.2%	1%
15	10C1	Delegation of major inspection authority	1	3%	0.2%	1%
16	6Q1	Statistical sampling inspection plans	1	3%	0.2%	1%
17	8Q3	Records of completed tests	1	3%	0.2%	1%
18	14C4	Relocation of manufacturing facility	1	3%	0.2%	0.4%
19	12Q5	Identification of age control products	1	3%	0.2%	0.3%
20	1M5	Policy document review	1	3%	0.2%	0.3%
21	10Q1	Initial & periodic evaluations of suppliers	1	3%	0.2%	0.3%
22	11Q2	Permanent identification of scrap material	1	3%	0.2%	0.3%
23	4Q1	Inspection methods and plans	1	3%	0.2%	0.3%
24	2E2	Drawing control system	1	3%	0.2%	0.3%
24	10Q10	Receiving inspection	1	3%	0.2%	0.3%
25	1Q4	Quality Manual	1	3%	0.2%	0.2%
		TOTAL	**74**			

TABLE C- 4.—Systemic findings and observations–APIS holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for APIS Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	5Q2	Required qualifications/approvals	1	9%	1%	2%
2	7Q11	Control of production tooling	1	9%	1%	1%
3	12Q5	Identification of age control products	1	9%	1%	1%
4	11Q4	Material review record generated	1	9%	1%	1%
5	4P1	Change approval	1	9%	1%	1%
6	4P4	Work instructions control manufacturing processes	1	9%	1%	1%
6	7Q1	Approval/inspection of tools & gauges	1	9%	1%	1%
7	4Q12	Completion of all inspections & tests	1	9%	1%	1%
8	2E3	Technical data change approval	1	9%	1%	1%
8	7Q12	Calibration records	1	9%	1%	1%
9	4Q5	Inspection records	1	9%	1%	1%
		TOTAL	**11**			

TABLE C- 5.—Systemic findings and observations–PC holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4Q1	Inspection methods and plans	7	6%	19%	21%
2	10Q1	Initial & periodic evaluations of suppliers	6	5%	16%	21%
3	15M1	Internal auditing program	6	5%	16%	20%
4	10Q5	Flow down of technical & quality requirements	4	3%	11%	15%
5	10Q10	Receiving inspection	4	3%	11%	14%
6	5E1	All special processes in use identified	4	3%	11%	13%
7	7Q3	Tool & gauge recall system	4	3%	11%	13%
8	4P4	Work instructions control manufacturing processes	4	3%	11%	12%
9	9Q3	NDI procedures/specifications available & used	3	2%	8%	12%
10	5Q3	Accord with process specifications	3	2%	8%	11%
11	11Q1	Control of nonconforming products	3	2%	8%	9%
12	4Q5	Inspection records	3	2%	8%	9%
12	12Q5	Identification of age control products	3	2%	8%	9%
13	4E1	Accord with FAA-approved design data	3	2%	8%	9%
14	9E2	Control of NDI processes & changes	2	2%	5%	8%
15	10Q6	Quality Assurance review of purchase documents	2	2%	5%	7%
16	12Q2	Special environmental controls	2	2%	5%	7%
17	1M1	Overall policy document	2	2%	5%	6%
17	8E1	Test procedures/instructions established	2	2%	5%	6%
17	12Q3	Storage of conforming parts	2	2%	5%	6%
18	7Q16	Inaccurate tools & gauges identified	2	2%	5%	6%
19	7Q1	Approval/inspection of tools & gauges	2	2%	5%	6%
20	2E7	Design/Technical data document control	2	2%	5%	6%

TABLE C- 5.—Systemic findings and observations–PC holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
21	4M1	Operation within production limitations	2	2%	5%	6%
22	3AE6	Software development environment	1	1%	3%	13%
22	3AP1	Software identification	1	1%	3%	13%
23	3AQ1	Programmed media handling/storage	1	1%	3%	10%
24	3AE1	Software Configuration Management Plan	1	1%	3%	9%
24	17Q6	Completion of all requirements	1	1%	3%	9%
25	10Q3	Approval of supplier quality manual	1	1%	3%	7%
26	6E1	Engineering review of SQC techniques	1	1%	3%	7%
27	3BE2	Change documentation and approval	1	1%	3%	6%
28	10Q4	Control of buyer-furnished material	1	1%	3%	5%
29	9Q4	Tanks & solutions checked	1	1%	3%	4%
30	2S2	Distribution of Inst. for Continued Airworthiness changes	1	1%	3%	4%
31	4Q7	Control of environmental conditions	1	1%	3%	4%
32	9Q9	Records of compliance	1	1%	3%	4%
32	14S2	Record of service difficulties	1	1%	3%	4%
33	11Q7	Corrective action monitored	1	1%	3%	4%
34	5Q4	Records maintained	1	1%	3%	4%
34	7Q9	Control of special processing equipment	1	1%	3%	4%
34	10Q8	Verification of raw material	1	1%	3%	4%
35	10Q2	Use of approved suppliers	1	1%	3%	3%
36	7Q6	Calibration & use in acceptable environment	1	1%	3%	3%
36	8E2	Control of test procedure/instruction changes	1	1%	3%	3%
36	10Q12	Records of receiving inspection	1	1%	3%	3%
36	11Q2	Permanent identification of scrap material	1	1%	3%	3%

TABLE C- 5.—Systemic findings and observations–PC holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
36	14C3	Submittal of quality system data changes	1	1%	3%	3%
37	2E3	Technical data change approval	1	1%	3%	3%
37	11E1	Engineering review for major/minor changes	1	1%	3%	3%
37	11Q4	Material review record generated	1	1%	3%	3%
38	4P5	Work instruction revision approval	1	1%	3%	3%
38	4Q9	Traceability to raw material	1	1%	3%	3%
38	7Q11	Control of production tooling	1	1%	3%	3%
39	2E1	Design change approval	1	1%	3%	3%
39	2E6	Storage of design documents	1	1%	3%	3%
39	4P1	Change approval	1	1%	3%	3%
39	4P2	Work instructions prepared	1	1%	3%	3%
39	4P9	Completed product/part identification	1	1%	3%	3%
39	4Q6	Cleaners, solvents, etc., identified	1	1%	3%	3%
39	7Q19	Tool & gauge rework /reinspection	1	1%	3%	3%
39	12Q1	Prevention of part damage /contamination	1	1%	3%	3%
40	1M2	Organizations described	1	1%	3%	3%
40	4P3	Work instructions reflect tech data	1	1%	3%	3%
40	7Q15	Care of tools & gauges	1	1%	3%	3%
40	7Q5	Accuracy of standards	1	1%	3%	3%
41	1M6	Policies /procedures availability	1	1%	3%	3%
41	1Q5	Tags, forms, etc., described	1	1%	3%	3%
41	4P6	Familiarity with specifications	1	1%	3%	3%
41	7Q12	Calibration records	1	1%	3%	3%
		TOTAL	**123**			

TABLE C- 6.—Systemic findings and observations–PMA holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	24	8%	10%	10%
2	10Q1	Initial & periodic evaluations of suppliers	15	5%	6%	8%
3	15M1	Internal auditing program	12	4%	5%	8%
4	5Q3	Accord with process specifications	11	3%	4%	9%
5	4M1	Operation within production limitations	11	3%	4%	5%
6	12Q3	Storage of conforming parts	11	3%	4%	5%
7	11Q1	Control of nonconforming products	10	3%	4%	4%
8	11Q2	Permanent identification of scrap material	9	3%	4%	5%
9	7Q12	Calibration records	9	3%	4%	4%
10	10Q8	Verification of raw material	9	3%	4%	4%
11	4Q5	Inspection records	9	3%	4%	4%
12	11Q4	Material review record generated	8	3%	3%	4%
13	10Q5	Flow down of technical & quality requirements	8	3%	3%	4%
14	10Q10	Receiving inspection	8	3%	3%	3%
15	12Q5	Identification of age control products	6	2%	2%	4%
16	4P5	Work instruction revision approval	6	2%	2%	3%
17	5Q2	Required qualifications/approvals	5	2%	2%	4%
18	4P4	Work instructions control manufacturing processes	5	2%	2%	2%
19	4P2	Work instructions prepared	5	2%	2%	2%
20	10Q2	Use of approved suppliers	5	2%	2%	2%
21	2E7	Design/Technical data document control	5	2%	2%	2%
22	7Q1	Approval/inspection of tools & gauges	5	2%	2%	2%
23	7Q6	Calibration & use in acceptable environment	4	1%	2%	2%
24	7Q3	Tool & gauge recall system	4	1%	2%	2%
25	2C1	Minor design change approval	4	1%	2%	2%

TABLE C- 6.—Systemic findings and observations–PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
26	4Q1	Inspection methods and plans	4	1%	2%	2%
27	2E1	Design change approval	4	1%	2%	2%
28	6Q1	Statistical sampling inspection plans	3	1%	1%	3%
29	7Q11	Control of production tooling	3	1%	1%	2%
30	7Q2	Instructions for acceptance tooling	3	1%	1%	2%
31	10Q6	Quality Assurance review of purchase documents	3	1%	1%	2%
32	4P3	Work instructions reflect tech data	3	1%	1%	1%
33	2E8	Major/minor design changes	3	1%	1%	1%
34	7Q14	Identification of gauges	3	1%	1%	1%
35	4E1	Accord with FAA-approved design data	3	1%	1%	1%
36	10Q12	Records of receiving inspection	3	1%	1%	1%
37	4Q12	Completion of all inspections & tests	3	1%	1%	1%
38	1Q4	Quality Manual	3	1%	1%	1%
39	3BE4	Software security	2	1%	1%	6%
40	9Q3	NDI procedures/specifications available & used	2	1%	1%	4%
41	12Q2	Special environmental controls	2	1%	1%	2%
42	5Q4	Records maintained	2	1%	1%	2%
43	8E2	Control of test procedure/instruction changes	2	1%	1%	1%
44	8E1	Test procedures/instructions established	2	1%	1%	1%
45	11Q6	Corrective action required	2	1%	1%	1%
46	10Q9	Verification of shelf-life materials	2	1%	1%	1%
47	4P1	Change approval	2	1%	1%	1%
48	7Q16	Inaccurate tools & gauges identified	2	1%	1%	1%
49	4Q3	Issuance of inspection stamps	2	1%	1%	1%
50	12Q7	Control of product removal/issuance	2	1%	1%	1%
51	2E3	Technical data change approval	2	1%	1%	1%

TABLE C- 6.—Systemic findings and observations–PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
52	4P6	Familiarity with specifications	2	1%	1%	1%
53	1Q6	Record retention schedule	2	1%	1%	1%
54	17Q2	Operation within certificate privileges	1	0.3%	0.4%	3%
54	17Q5	Record of completed work	1	0.3%	0.4%	3%
55	3BE3	Software problem reporting	1	0.3%	0.4%	3%
56	9Q4	Tanks & solutions checked	1	0.3%	0.4%	3%
57	9Q1	Operator qualification	1	0.3%	0.4%	2%
58	16Q3	Export airworthiness approvals obtained	1	0.3%	0.4%	2%
59	6Q10	Corrective action	1	0.3%	0.4%	2%
60	1E1	Engineering/Flight Test organizations described	1	0.3%	0.4%	1%
61	8Q3	Records of completed tests	1	0.3%	0.4%	1%
62	2E5	Changes to Instructions for Continued Airworthiness	1	0.3%	0.4%	1%
63	5Q1	Equipment available & calibrated	1	0.3%	0.4%	1%
64	2E4	AD incorporation into design	1	0.3%	0.4%	1%
65	7Q9	Control of special processing equipment	1	0.3%	0.4%	1%
66	7Q8	Use of personal gauges	1	0.3%	0.4%	1%
67	4P7	Identification/control of partially accepted parts	1	0.3%	0.4%	1%
68	1P3	Manufacturing staff qualifications	1	0.3%	0.4%	1%
68	4Q2	Location of inspection stations	1	0.3%	0.4%	1%
68	7Q13	Adjustment of calibration intervals	1	0.3%	0.4%	1%
69	14C3	Submittal of quality system data changes	1	0.3%	0.4%	1%
70	1Q3	Quality Assurance staff qualifications	1	0.3%	0.4%	1%
71	11E1	Engineering review for major/minor changes	1	0.3%	0.4%	1%
71	11Q3	MRB established and operational	1	0.3%	0.4%	1%
72	4Q11	Inspection before closure	1	0.3%	0.4%	1%
73	11M1	Management review of data	1	0.3%	0.4%	1%
74	1M5	Policy document review	1	0.3%	0.4%	1%
74	2Q1	QA review of design/technical data changes	1	0.3%	0.4%	1%

TABLE C- 6.—Systemic findings and observations–PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
75	14C1	Failure reporting	1	0.3%	0.4%	1%
76	2C2	Major design change approval	1	0.3%	0.4%	0.5%
77	7Q5	Accuracy of standards	1	0.3%	0.4%	0.5%
78	1Q2	Quality Assurance Manager identified	1	0.3%	0.4%	0.5%
79	1Q1	Quality organizations described	1	0.3%	0.4%	0.5%
80	4Q10	Inspection marking	1	0.3%	0.4%	0.5%
81	1Q5	Tags, forms, etc., described	1	0.3%	0.4%	0.5%
82	7Q4	Traceability to national/international standards	1	0.3%	0.4%	0.4%
83	2E9	Technical data file	1	0.3%	0.4%	0.4%
84	2E6	Storage of design documents	1	0.3%	0.4%	0.4%
85	2E2	Drawing control system	1	0.3%	0.4%	0.4%
85	12Q4	Segregation of product in storage	1	0.3%	0.4%	0.4%
		TOTAL	**317**			

TABLE C- 7.—Systemic findings and observations–priority parts suppliers only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for Suppliers	Percent of Facilities	Percent of Applicable Facilities with Issues
1	15M1	Internal auditing program	2	10%	5%	6%
2	9E1	Engineering review of NDI processes	1	5%	3%	7%
3	6Q1	Statistical sampling inspection plans	1	5%	3%	6%
4	5Q3	Accord with process specifications	1	5%	3%	6%
5	2E3	Technical data change approval	1	5%	3%	5%
6	4M1	Operation within production limitations	1	5%	3%	5%
7	10Q1	Initial & periodic evaluations of suppliers	1	5%	3%	4%
8	10Q7	Action on problem notification	1	5%	3%	4%
9	2E2	Drawing control system	1	5%	3%	3%
10	1M5	Policy document review	1	5%	3%	3%
10	10Q2	Use of approved suppliers	1	5%	3%	3%
11	11Q2	Permanent identification of scrap material	1	5%	3%	3%
12	4P9	Completed product/part identification	1	5%	3%	3%
13	11Q1	Control of nonconforming products	1	5%	3%	3%
14	4P4	Work instructions control manufacturing processes	1	5%	3%	3%
14	4Q1	Inspection methods and plans	1	5%	3%	3%
15	1Q4	Quality Manual	1	5%	3%	3%
16	4Q12	Completion of all inspections & tests	1	5%	3%	3%
16	7Q14	Identification of gauges	1	5%	3%	3%
16	12Q4	Segregation of product in storage	1	5%	3%	3%
		TOTAL	**21**			

TABLE C- 8.—Systemic findings and observations–TSO authorization holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSO Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	15M1	Internal auditing program	10	6%	10%	14%
2	10Q1	Initial & periodic evaluations of suppliers	8	5%	8%	10%
3	2C4	Data submittal for TSO minor changes	7	4%	7%	8%
4	5Q3	Accord with process specifications	6	4%	6%	11%
5	10Q2	Use of approved suppliers	6	4%	6%	7%
6	4Q12	Completion of all inspections & tests	6	4%	6%	6%
7	2C1	Minor design change approval	5	3%	5%	7%
8	10Q5	Flow down of technical & quality requirements	4	2%	4%	5%
9	4P4	Work instructions control manufacturing processes	4	2%	4%	4%
10	10Q10	Receiving inspection	4	2%	4%	4%
11	1Q4	Quality Manual	4	2%	4%	4%
12	11Q4	Material review record generated	3	2%	3%	4%
13	10Q6	Quality Assurance review of purchase documents	3	2%	3%	4%
14	7Q3	Tool & gauge recall system	3	2%	3%	3%
15	11Q2	Permanent identification of scrap material	3	2%	3%	3%
16	1Q6	Record retention schedule	3	2%	3%	3%
17	7Q1	Approval/inspection of tools & gauges	3	2%	3%	3%
18	11Q1	Control of nonconforming products	3	2%	3%	3%
19	2E2	Drawing control system	3	2%	3%	3%
20	2E9	Technical data file	3	2%	3%	3%
20	4P9	Completed product/part identification	3	2%	3%	3%
21	4E1	Accord with FAA-approved design data	3	2%	3%	3%
21	4M1	Operation within production limitations	3	2%	3%	3%
21	4Q5	Inspection records	3	2%	3%	3%

TABLE C- 8.—Systemic findings and observations–TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSO Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
22	13E1	AD incorporation	2	1%	2%	4%
23	14C3	Submittal of quality system data changes	2	1%	2%	3%
24	7Q11	Control of production tooling	2	1%	2%	3%
25	8E2	Control of test procedure/instruction changes	2	1%	2%	2%
26	8E1	Test procedures/instructions established	2	1%	2%	2%
27	12Q1	Prevention of part damage/contamination	2	1%	2%	2%
28	4Q2	Location of inspection stations	2	1%	2%	2%
29	7P1	Appropriate measuring devices used	2	1%	2%	2%
30	12Q3	Storage of conforming parts	2	1%	2%	2%
31	7Q15	Care of tools & gauges	2	1%	2%	2%
32	2E3	Technical data change approval	2	1%	2%	2%
32	4Q1	Inspection methods and plans	2	1%	2%	2%
32	7Q12	Calibration records	2	1%	2%	2%
33	9E2	Control of NDI processes & changes	1	1%	1%	8%
33	9Q14	Critical penetrant parameters identified	1	1%	1%	8%
34	9Q1	Operator qualification	1	1%	1%	7%
35	3AE1	Software Configuration Management Plan	1	1%	1%	5%
35	6Q10	Corrective action	1	1%	1%	5%
36	3BE4	Software security	1	1%	1%	5%
37	3BE2	Change documentation and approval	1	1%	1%	5%
37	3BQ1	Verification prior to use	1	1%	1%	5%
38	16Q5	Documents to importing country	1	1%	1%	3%
39	10Q3	Approval of supplier quality manual	1	1%	1%	2%
40	8Q3	Records of completed tests	1	1%	1%	2%
41	7Q9	Control of special processing equipment	1	1%	1%	2%
42	5E1	All special processes in use identified	1	1%	1%	2%
43	4Q7	Control of environmental conditions	1	1%	1%	2%
44	4P8	Traceability for split lots	1	1%	1%	2%

TABLE C- 8.—Systemic findings and observations–TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSO Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
45	2C2	Major design change approval	1	1%	1%	2%
46	2C5	New TSOA for major design changes	1	1%	1%	1%
47	12Q5	Identification of age control products	1	1%	1%	1%
48	11Q7	Corrective action monitored	1	1%	1%	1%
49	11E1	Engineering review for major/minor changes	1	1%	1%	1%
49	11Q5	Reinspection/retest after rework/repair	1	1%	1%	1%
50	4Q6	Cleaners, solvents, etc., identified	1	1%	1%	1%
51	7Q6	Calibration & use in acceptable environment	1	1%	1%	1%
51	11Q6	Corrective action required	1	1%	1%	1%
52	4Q3	Issuance of inspection stamps	1	1%	1%	1%
52	4Q9	Traceability to raw material	1	1%	1%	1%
53	7Q5	Accuracy of standards	1	1%	1%	1%
53	12Q8	Conforming products packaged & shipped	1	1%	1%	1%
54	2E8	Major/minor design changes	1	1%	1%	1%
55	4P3	Work instructions reflect tech data	1	1%	1%	1%
56	4P6	Familiarity with specifications	1	1%	1%	1%
56	7Q7	Accuracy of inspection & test equipment	1	1%	1%	1%
56	10Q8	Verification of raw material	1	1%	1%	1%
57	2E1	Design change approval	1	1%	1%	1%
57	2E7	Design/Technical data document control	1	1%	1%	1%
57	7Q4	Traceability to national/international standards	1	1%	1%	1%
58	2E6	Storage of design documents	1	1%	1%	1%
59	7Q14	Identification of gauges	1	1%	1%	1%
59	10Q12	Records of receiving inspection	1	1%	1%	1%
		TOTAL	**168**			

TABLE C- 9.—Isolated observations–APIS holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for APIS Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	8E3	Approved flight checkoff form	1	20%	1%	100%
2	10Q9	Verification of shelf-life materials	1	20%	1%	1%
3	4Q3	Issuance of inspection stamps	1	20%	1%	1%
4	7Q16	Inaccurate tools & gauges identified	1	20%	1%	1%
5	4Q1	Inspection methods and plans	1	20%	1%	1%
		TOTAL	**5**			

TABLE C- 10.—Isolated observations–PC holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	12Q5	Identification of age control products	6	9%	16%	18%
2	10Q1	Initial & periodic evaluations of suppliers	5	7%	14%	17%
3	11Q1	Control of nonconforming products	3	4%	8%	9%
4	6Q1	Statistical sampling inspection plans	2	3%	5%	12%
5	7Q10	Control of NDI Equipment	2	3%	5%	8%
6	5Q4	Records maintained	2	3%	5%	7%
7	15M1	Internal auditing program	2	3%	5%	7%
8	11Q3	MRB established and operational	2	3%	5%	6%
9	12Q3	Storage of conforming parts	2	3%	5%	6%
10	2E1	Design change approval	2	3%	5%	6%
11	2E2	Drawing control system	2	3%	5%	6%
12	1Q5	Tags, forms, etc., described	2	3%	5%	6%
12	2E7	Design/Technical data document control	2	3%	5%	6%
13	3AE2	Configuration Index Document	1	1%	3%	9%
13	17Q3	Work in accordance with Part 43 requirements	1	1%	3%	9%
14	6Q10	Corrective action	1	1%	3%	8%
15	6P1	Manufacturing review of SQC techniques	1	1%	3%	7%
15	10Q3	Approval of supplier quality manual	1	1%	3%	7%
16	3BQ1	Verification prior to use	1	1%	3%	6%
17	9Q13	Critical magnetic particle parameters identified	1	1%	3%	6%
18	13Q1	Log books	1	1%	3%	5%
19	9Q14	Critical penetrant parameters identified	1	1%	3%	4%
20	10E1	Control of supplier design and changes	1	1%	3%	4%
21	9Q9	Records of compliance	1	1%	3%	4%
22	10Q5	Flow down of technical & quality requirements	1	1%	3%	4%

TABLE C- 10.— Isolated observations–PC holders only —Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
23	5Q3	Accord with process specifications	1	1%	3%	4%
23	8Q1	QA review of test instructions	1	1%	3%	4%
23	10Q10	Receiving inspection	1	1%	3%	4%
23	10Q8	Verification of raw material	1	1%	3%	4%
24	10Q2	Use of approved suppliers	1	1%	3%	3%
24	10Q7	Action on problem notification	1	1%	3%	3%
24	11Q6	Corrective action required	1	1%	3%	3%
25	7Q6	Calibration & use in acceptable environment	1	1%	3%	3%
25	8E2	Control of test procedure/instruction changes	1	1%	3%	3%
25	11Q2	Permanent identification of scrap material	1	1%	3%	3%
25	14C3	Submittal of quality system data changes	1	1%	3%	3%
26	1M4	FAA designee authority	1	1%	3%	3%
26	4P5	Work instruction revision approval	1	1%	3%	3%
26	8E1	Test procedures/instructions established	1	1%	3%	3%
27	12Q1	Prevention of part damage/contamination	1	1%	3%	3%
27	12Q4	Segregation of product in storage	1	1%	3%	3%
28	4P4	Work instructions control manufacturing processes	1	1%	3%	3%
28	4Q1	Inspection methods and plans	1	1%	3%	3%
28	4Q10	Inspection marking	1	1%	3%	3%
28	7Q15	Care of tools & gauges	1	1%	3%	3%
28	7Q4	Traceability to national/international standards	1	1%	3%	3%
28	7Q7	Accuracy of inspection & test equipment	1	1%	3%	3%
29	1Q4	Quality Manual	1	1%	3%	3%
		TOTAL	**69**			

TABLE C- 11.— Isolated observations–PMA holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	5	9%	2%	3%
2	7Q1	Approval/inspection of tools & gauges	5	9%	2%	2%
3	15M1	Internal auditing program	4	7%	2%	3%
4	4P9	Completed product/part identification	4	7%	2%	2%
5	12Q5	Identification of age control products	3	6%	1%	2%
6	10Q1	Initial & periodic evaluations of suppliers	3	6%	1%	2%
7	10Q5	Flow down of technical & quality requirements	2	4%	1%	1%
8	7Q14	Identification of gauges	2	4%	1%	1%
9	2E1	Design change approval	2	4%	1%	1%
10	2E7	Design/Technical data document control	2	4%	1%	1%
11	11Q1	Control of nonconforming products	2	4%	1%	1%
12	8Q3	Records of completed tests	1	2%	0.4%	1%
13	7Q18	Action on product measured by SOT gauge	1	2%	0.4%	1%
14	5Q1	Equipment available & calibrated	1	2%	0.4%	1%
15	4Q7	Control of environmental conditions	1	2%	0.4%	1%
16	5Q4	Records maintained	1	2%	0.4%	1%
17	5Q3	Accord with process specifications	1	2%	0.4%	1%
18	5E1	All special processes in use identified	1	2%	0.4%	1%
19	8E1	Test procedures/instructions established	1	2%	0.4%	1%
20	7Q13	Adjustment of calibration intervals	1	2%	0.4%	1%
21	11Q6	Corrective action required	1	2%	0.4%	1%
22	2C2	Major design change approval	1	2%	0.4%	0.5%
23	4P3	Work instructions reflect tech data	1	2%	0.4%	0.5%

TABLE C- 11.— Isolated observations–PMA holders only —Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
24	4P4	Work instructions control manufacturing processes	1	2%	0.4%	0.5%
25	7Q3	Tool & gauge recall system	1	2%	0.4%	0.5%
26	2C1	Minor design change approval	1	2%	0.4%	0.5%
27	4Q3	Issuance of inspection stamps	1	2%	0.4%	0.5%
28	12Q1	Prevention of part damage/contamination	1	2%	0.4%	0.5%
29	10Q8	Verification of raw material	1	2%	0.4%	0.4%
30	12Q3	Storage of conforming parts	1	2%	0.4%	0.4%
31	10Q10	Receiving inspection	1	2%	0.4%	0.4%
		TOTAL	**54**			

TABLE C- 12..— Isolated observations– priority parts suppliers only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for Suppliers	Percent of Facilities	Percent of Applicable Facilities with Issues
1	3BE1	Software Configuration Management Plan	1	7%	3%	14%
2	5Q3	Accord with process specifications	1	7%	3%	6%
3	2E1	Design change approval	1	7%	3%	5%
4	10Q1	Initial & periodic evaluations of suppliers	1	7%	3%	4%
5	15M2	Feedback to higher-level management	1	7%	3%	3%
6	2E2	Drawing control system	1	7%	3%	3%
6	15M1	Internal auditing program	1	7%	3%	3%
7	7Q6	Calibration & use in acceptable environment	1	7%	3%	3%
8	4P3	Work instructions reflect tech data	1	7%	3%	3%
8	4P4	Work instructions control manufacturing processes	1	7%	3%	3%
8	4Q1	Inspection methods and plans	1	7%	3%	3%
9	4Q5	Inspection records	1	7%	3%	3%
9	7Q14	Identification of gauges	1	7%	3%	3%
9	12Q3	Storage of conforming parts	1	7%	3%	3%
		TOTAL	**14**			

TABLE C- 13.— Isolated observations–TSO authorization holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for TSO Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	5	8%	5%	6%
2	11Q1	Control of nonconforming products	5	8%	5%	5%
3	4Q5	Inspection records	4	6%	4%	4%
4	10Q1	Initial & periodic evaluations of suppliers	3	5%	3%	4%
5	7Q3	Tool & gauge recall system	3	5%	3%	3%
6	4P4	Work instructions control manufacturing processes	3	5%	3%	3%
7	2E1	Design change approval	3	5%	3%	3%
8	2E2	Drawing control system	3	5%	3%	3%
9	15M1	Internal auditing program	2	3%	2%	3%
10	10Q9	Verification of shelf-life materials	2	3%	2%	2%
11	2C4	Data submittal for TSO minor changes	2	3%	2%	2%
11	10Q5	Flow down of technical & quality requirements	2	3%	2%	2%
12	10Q2	Use of approved suppliers	2	3%	2%	2%
13	7Q1	Approval/inspection of tools & gauges	2	3%	2%	2%
14	4Q12	Completion of all inspections & tests	2	3%	2%	2%
15	1Q4	Quality Manual	2	3%	2%	2%
16	7Q14	Identification of gauges	2	3%	2%	2%
17	9E2	Control of NDI processes & changes	1	2%	1%	8%
17	9Q3	NDI procedures/specifications available & used	1	2%	1%	8%
18	17Q5	Record of completed work	1	2%	1%	5%
19	3AE1	Software Configuration Management Plan	1	2%	1%	5%
20	5Q2	Required qualifications/approvals	1	2%	1%	2%
21	4P7	Identification/control of partially accepted parts	1	2%	1%	1%
22	4E2	New/changed process test substantiation	1	2%	1%	1%

TABLE C- 13.— Isolated observations –TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for TSO Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
23	12Q5	Identification of age control products	1	2%	1%	1%
24	8Q1	QA review of test instructions	1	2%	1%	1%
25	4P5	Work instruction revision approval	1	2%	1%	1%
25	4Q3	Issuance of inspection stamps	1	2%	1%	1%
26	8E1	Test procedures/instructions established	1	2%	1%	1%
27	4P2	Work instructions prepared	1	2%	1%	1%
28	7Q15	Care of tools & gauges	1	2%	1%	1%
29	4Q1	Inspection methods and plans	1	2%	1%	1%
29	7Q12	Calibration records	1	2%	1%	1%
30	2E9	Technical data file	1	2%	1%	1%
30	4P9	Completed product/part identification	1	2%	1%	1%
31	4E1	Accord with FAA-approved design data	1	2%	1%	1%
		TOTAL	**66**			

TABLE C- 14.— Systemic findings and observations –international facilities

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	2E7	Design/Technical data document control	6	8%	30%	30%
2	5Q3	Accord with process specifications	4	5%	20%	24%
3	7Q11	Control of production tooling	3	4%	15%	18%
4	10Q1	Initial & periodic evaluations of suppliers	3	4%	15%	19%
5	11Q6	Corrective action required	3	4%	15%	17%
6	1M6	Policies/procedures availability	2	3%	10%	11%
7	4P1	Change approval	2	3%	10%	10%
7	4P4	Work instructions control manufacturing processes	2	3%	10%	10%
8	4P7	Identification/control of partially accepted parts	2	3%	10%	14%
9	5Q4	Records maintained	2	3%	10%	12%
10	11Q7	Corrective action monitored	2	3%	10%	11%
11	12Q1	Prevention of part damage/contamination	2	3%	10%	11%
11	12Q3	Storage of conforming parts	2	3%	10%	11%
12	15M1	Internal auditing program	2	3%	10%	10%
13	1M5	Policy document review	1	1%	5%	6%
13	2E1	Design change approval	1	1%	5%	6%
14	2E2	Drawing control system	1	1%	5%	5%
15	2E3	Technical data change approval	1	1%	5%	6%
16	2E9	Technical data file	1	1%	5%	5%
17	2P1	Manufacturing review of design/technical data changes	1	1%	5%	9%
18	4E2	New/changed process test substantiation	1	1%	5%	6%
19	4P2	Work instructions prepared	1	1%	5%	5%
19	4P5	Work instruction revision approval	1	1%	5%	5%
19	4P6	Familiarity with specifications	1	1%	5%	5%
19	4Q1	Inspection methods and plans	1	1%	5%	5%
19	4Q12	Completion of all inspections & tests	1	1%	5%	5%
19	4Q5	Inspection records	1	1%	5%	5%
19	4Q9	Traceability to raw material	1	1%	5%	5%

TABLE C- 14.— Systemic findings and observations –international facilities —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
20	5E1	All special processes in use identified	1	1%	5%	5%
21	5Q1	Equipment available & calibrated	1	1%	5%	6%
22	5Q2	Required qualifications/approvals	1	1%	5%	6%
23	5Q5	Action on process out of control	1	1%	5%	6%
24	6Q10	Corrective action	1	1%	5%	20%
25	6Q9	Regular review of SPC charts	1	1%	5%	17%
26	7Q1	Approval/inspection of tools & gauges	1	1%	5%	5%
26	7Q12	Calibration records	1	1%	5%	5%
27	7Q13	Adjustment of calibration intervals	1	1%	5%	7%
28	7Q14	Identification of gauges	1	1%	5%	5%
29	7Q4	Traceability to national/international standards	1	1%	5%	6%
30	7Q6	Calibration & use in acceptable environment	1	1%	5%	5%
31	9E1	Engineering review of NDI processes	1	1%	5%	6%
32	9E2	Control of NDI processes & changes	1	1%	5%	6%
33	9Q1	Operator qualification	1	1%	5%	6%
34	9Q14	Critical penetrant parameters identified	1	1%	5%	6%
35	9Q5	Test pieces/samples available	1	1%	5%	6%
36	10C1	Delegation of major inspection authority	1	1%	5%	20%
37	10E1	Control of supplier design and changes	1	1%	5%	14%
38	10Q12	Records of receiving inspection	1	1%	5%	5%
39	10Q5	Flow down of technical & quality requirements	1	1%	5%	6%
40	11Q1	Control of nonconforming products	1	1%	5%	5%
41	12Q2	Special environmental controls	1	1%	5%	6%
42	12Q7	Control of product removal/issuance	1	1%	5%	6%
		TOTAL	**75**			

TABLE C- 15.—Isolated observations –international facilities

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	5Q3	Accord with process specifications	3	8%	15%	18%
2	2E7	Design/Technical data document control	3	8%	15%	15%
2	4P4	Work instructions control manufacturing processes	3	8%	15%	15%
3	10Q1	Initial & periodic evaluations of suppliers	2	5%	10%	13%
4	4Q4	Inspection stamps & damage to material	2	5%	10%	11%
5	12Q1	Prevention of part damage/contamination	2	5%	10%	11%
5	2E2	Drawing control system	2	5%	10%	11%
6	15M1	Internal auditing program	2	5%	10%	10%
6	4Q8	Traceable components identified	2	5%	10%	10%
7	6Q10	Corrective action	1	3%	5%	20%
8	6Q1	Statistical sampling inspection plans	1	3%	5%	13%
9	3BE4	Software security	1	3%	5%	10%
10	9Q14	Critical penetrant parameters identified	1	3%	5%	6%
11	12Q5	Identification of age control products	1	3%	5%	6%
11	1P3	Manufacturing staff qualifications	1	3%	5%	6%
11	5Q4	Records maintained	1	3%	5%	6%
12	10Q11	Segregation of non-certificated parts	1	3%	5%	6%
12	2E3	Technical data change approval	1	3%	5%	6%
13	10Q10	Receiving inspection	1	3%	5%	5%
13	12Q4	Segregation of product in storage	1	3%	5%	5%
13	7Q12	Calibration records	1	3%	5%	5%
14	4P2	Work instructions prepared	1	3%	5%	5%
14	4P5	Work instruction revision approval	1	3%	5%	5%
14	4P6	Familiarity with specifications	1	3%	5%	5%
14	4Q1	Inspection methods and plans	1	3%	5%	5%
14	4Q10	Inspection marking	1	3%	5%	5%
		TOTAL	**38**			

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APPENDIX D
CORRELATION BETWEEN FACILITY COMPLEXITY AND THE PROBABILITY OF SYSTEMIC ISSUES

When comparisons among facilities were initially made, PC holders appeared to have a greater incidence of noncompliance than other facility types. However, we believe that this direct comparison between the facility types is biased. It was hypothesized that the larger facilities with complex systems would have a greater chance of having findings and observations than small facilities with simple systems, regardless of their facility types. For example, a 20,000-employee supplier of a complex assembly would have a greater chance of having discrepancies than a four-employee supplier – simply due to the differences in their sizes and nature of their systems. There are only a handful of PC holders with a small number of employees and operating under simplistic quality systems; however, there are several priority parts suppliers, PMA holders, and TSO authorization holders who are small and operate under simple systems. Therefore, comparing PC holders to suppliers without compensating for their varying size and complexity would be inappropriate. The obvious solution would be to compare facilities of similar size and complexity. A method was investigated to account for these differences and make the necessary adjustments to the analysis in order to make comparisons between the different facility types without this bias.

Several regression analyses were performed to find a compensating factor that could be used to predict the direct correlation between facility complexity and the probability of systemic noncompliance. The number of evaluators, duration of the evaluations, total evaluator hours expended, the size of the facilities, and the type of facilities were all explored.

These analyses showed that the most reliable indicator of facility complexity was the number of evaluators present on an evaluation. This is because the number of evaluators selected to properly conduct an ACSEP evaluation is determined prior to the evaluation with careful consideration to: a facility's size, physical layout, number and type of certificates held, number of applicable subsystems, product number and complexity, number of employees associated with these products, the number of procedures controlling these products, and any unique or special circumstances. Therefore, the number of evaluators would logically be the more comprehensive indicator of facility complexity. Evaluation duration and evaluator hours expended also incorporate the elements just listed, and therefore, were also analyzed in detail. Facility size and type were ruled out as not being comprehensive measures of facility complexity as they consider only one element of complexity each.

The analyses support the hypothesis that the number of evaluators relates to facility complexity with a very strong direct correlation (a 97 percent coefficient of dependence between the number of evaluators and the probability of findings and observations). There

is no correlation between evaluation duration and the probability of findings or observations. The analysis indicated a direct correlation between the probability of systemic issues and the number of evaluator hours expended on the evaluation (a measure of the complexity of the evaluation); however, this correlation was weak (55 percent coefficient of dependence). The number of evaluators appeared to be the best factor for determining facility complexity, and was, therefore, selected to normalize the incidence of noncompliance between the facility types.

It should be noted that the number of evaluators is neither a guarantee of findings nor is it in itself the determinant of the probability of a facility getting findings. There were several occurrences of large evaluation teams not finding any systemic issues and several occurrences of small evaluation teams finding several systemic issues. This would support the theorem that the number of evaluators is only an indicator of facility complexity. By possessing a greater number of procedures and policies, more complex systems would have a higher probability of being in noncompliance. The probability of noncompliance does not, in itself, relate to the number of evaluators. Conversely, the number of evaluators, in itself, does not relate to the number of noncompliances (weak coefficient of dependence as seen in *figure D-1*). The number of evaluators is a measure of facility complexity; complexity relates to the number of possibilities for noncompliance; the number of possibilities for noncompliance defines the probability for noncompliance; and the probability for noncompliance determines the number of findings.

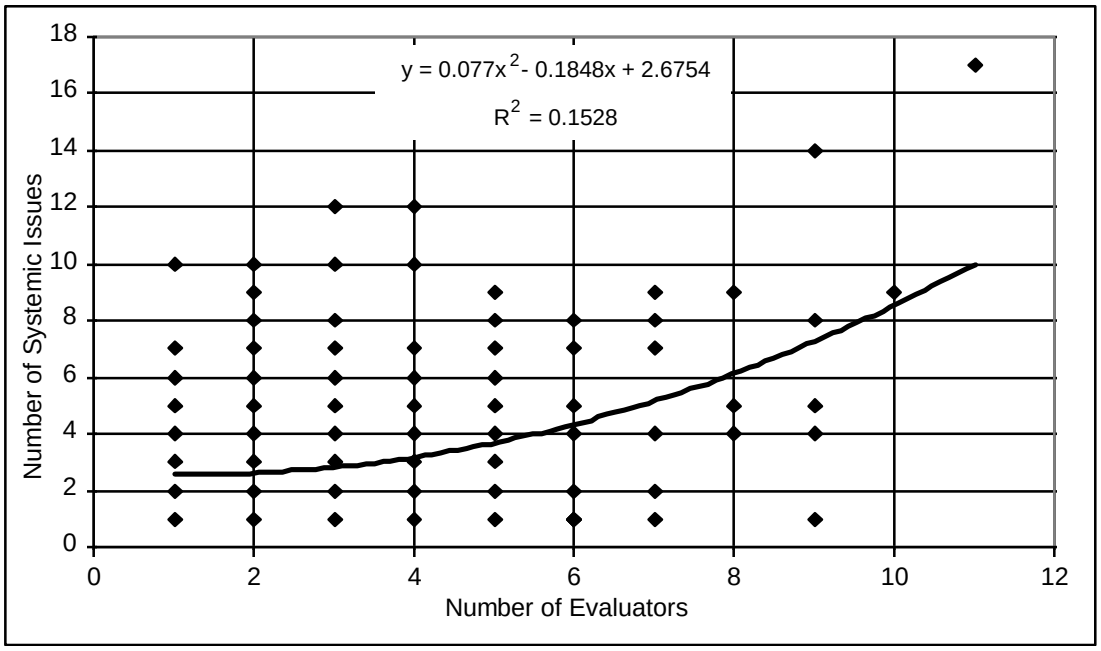

Figure D-1.—Scatter diagram of systemic findings/observations vs. number of evaluators present at ACSEP evaluations.

APPENDIX E
ANALYSIS METHODS AND ASSUMPTIONS

E1. Prediction Error

One of the purposes of an ACSEP evaluation is to test a facility's compliance with the FAR and its own established policies and procedures. In a very small facility with very few procedures and low production, the test for compliance could be a 100 percent check of all available data. For all other facilities, however, a 100 percent check of all available data would be extremely time consuming, uneconomical, and disruptive to the facility's productivity with only minimal data enhancement. For all except the smallest of facilities, the widely accepted practice of examining only a portion of the available data and extrapolating the results to conclusions about the balance of the data not reviewed is used. The examination of a small portion of the available data and drawing conclusions about the whole of a facility is defined as a sampling process.

There is no guarantee that the sample of data selected to be evaluated will reflect the exact condition of all of the available data from which the sample was selected. Additionally, the type of sample chosen (unrestricted random, stratified, clustered, multistage, etc.) is open to the best judgment of the evaluator. The information available to the evaluator at the time this judgment is made may not be complete. Since no evaluator is infallible, there is also no guarantee that the type or size of sample chosen from the available data will be the most ideal to reflect the exact condition of compliance for that facility. Sample error within the evaluation of each facility is thereby introduced into any analysis of data derived from these individual evaluations.

The figures and tables that report compliance rates shown in the *Executive Summary, Section 3, and Appendix C* of this report correctly reflect the results of all of the evaluations performed within the time period specified. Statements as to the compliance rate of those particular facilities evaluated can be made directly off the charts. Any error introduced into these evaluations by the sampling of available data at those facilities is unique to those individual facilities and is not separately reported. Since every evaluation is performed only by trained evaluators, error introduced into the individual facilities' evaluations is considered relatively small.

Use of the data from the evaluations analyzed in this report to predict industry trends, as opposed to simply reporting historical results, is subject to the statistical principle of sample error. For clarity, the term "prediction error" is used in this report to identify the amount of sample error present in those analyses used to report or trend compliance rate. (For clarity, the term "sample error" is also used under specific conditions that will be explained later in this appendix.). The size of the prediction (sample) error is simply a factor of the sample size (number of findings and/or observations) being reported and is in no way a qualitative measure of the evaluations performed. Using *figure 3-3* as an

example, 26 percent of the facilities evaluated for FY 1997 had systemic manufacturing process issues, and those manufacturing process issues made up 24 percent of all of the systemic issues for FY 1997. In addition, the data can be used to predict, within a 95 percent confidence level, that no less than 22 percent and no more than 30 percent (26 percent ± 4 percent) of *all* facilities have systemic issues with compliance in manufacturing processes. Please note that the four percent prediction error is only a measure of the reliability of predictions based on the data and is not a measure of the accuracy of the data itself.

Due to limited time and resources, evaluators focus their attention on selected samples of available data; exhaustive evaluations of every piece of data over long periods of time are not practical and would interfere with production. The use of sampling, good evaluation judgment, and skilled evaluators will produce an evaluation report that statistically reflects compliance issues for a particular facility for a particular period of time. However, these limiting factors also limit the total number of potential findings and observations reported. Given unlimited time and resources, there theoretically could be an indeterminate number of findings or observations. Lacking a finite number of possible findings or observations, the population size of possible findings or observations is, therefore, assumed to be large. Based on this assumption, the equation used to calculate the prediction error is:

$$PE_{\%} = \pm z\sqrt{\frac{p(1-p)}{n}} \qquad (1)$$

where $PE_{\%}$ = prediction error
z = confidence coefficient factor
p = percent of facilities with findings and/or observations
n = sample size (number of finding and/or observations)

E2. Sample Error - Finite Populations

This report contains the results of tests seeking to determine differences between two or more sets of various data. Unlike the analyses mentioned above, which compare finite sets of data to a theoretically infinite population size, tests for significant differences and hypothesis testing compare finite sets of data with other finite sets of data. The use of a finite population affects the error rate, especially when the sample size is greater than five percent of the population size. The term “sample error” is used in this report to distinguish between analyses where the population is finite and those where the population is considered infinite, as discussed above as “prediction error.” To adjust for this difference, equation (1) is modified as follows:

$$SE_{\%} = \pm z\sqrt{\frac{p(1-p)}{n}}\sqrt{\frac{N-n}{N-1}} \qquad (2)$$

where $SE_{\%}$ = sample error
z = confidence coefficient factor
p = percent of facilities with findings and/or observations
n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)
N = population size

Equation (2) proves adequate if the sample size is equal to or greater than 30. Should the sample size be less than 30, or the proportion be too close to zero or one-hundred percent (if the product $pn < 5$ or the product $(1\text{-}p)n < 5$), equation (3) is used to determine the limits of the analysis.

$$p_{\text{lim}} = \frac{p + \frac{z^2}{2n} \pm z\sqrt{\frac{p(1-p)}{n} + \frac{z^2}{4n^2}}}{1 + \frac{z^2}{n}} \qquad (3)$$

where p_{lim} = upper and lower confidence limit of the analysis
z = confidence coefficient factor
p = percent of facilities with findings and/or observations
n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)

E3. Pooling of Multi-year Data

The pooling of two fiscal years of data is considered a justifiable method of strengthening the reliability of the analyses since it does not introduce any additional variants into the analysis. Because the shortest time interval between an ACSEP evaluation being repeated at any one facility is two years, pooling of two years of data represents an analysis of only one evaluation from any one facility. Additionally, statistical analysis has shown no significant variance between the two years of data (except as noted for PC holders[16] — this shift in PC holder data is theorized to be a factor of initial bias introduced at the start of the ACSEP and not a function of any industry fluctuation). Therefore, the two sets of data, for example that from FY 1996 and from FY 1997, are considered to be from the same total population and pooling the two sets of data in some of the analyses used in this report is considered justified.

E4. Selection of the Confidence Interval

The conclusions reached in this report are based on analyses of a finite set of data (i.e., sample data). Statements made concerning probability distributions of the true population are base upon the results of this sample data and are thereby subject to statistical error. This statistical error is divided into two types: noting a significant difference in the samples when there is none –– Type I error, and the failure to note a significant difference when a significant difference does exist –– Type II error. Attempts to limit the probability of Type I errors (denoted by α) generally increase the likelihood of Type II errors (denoted by β). The only way to simultaneously eliminate both types of errors is to increase the sample size. The confidence intervals selected for the individual analyses attempts to balance the possibility of these two types of error. In those analyses where one type of error may have more serious consequences than the other, a confidence level is selected to limit the more severe of the two error types.

Analysis performed on the data to determine the frequency distribution of the findings and observations divides the data into several discrete categories, i.e., 17 subsystems. In addition, the sample sizes are relatively low; e.g., the sample size of domestic PC holders for FY 1997 is 37 facilities having a total of 124 findings and/or systemic observations among them. This already small sample size is further divided into the occurrences within 17 subsystems and 225 different criteria elements. A 95 percent confidence interval was used in order to highlight the differences among the various subsystems while maintaining a reasonable limit of Type II errors.

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[16] A significant difference between FY 1995 and FY 1996 and between FY 1996 and FY 1997 was noted for PC holders at the 90 percent confidence level. The difference was not significant at the 95 percent level. Given the theory that the difference noted between any two consecutive years was caused by initial facility selection bias, pooling of the data would represent a means to attain the random sample required in order for the analysis to be valid. See *Section E4* of this appendix for clarification as to the selection of the confidence level.

Some of the analyses in this report test for significant differences among a few (typically four or less) proportions in an attempt to highlight potential variations in the samples. Because of the consequences associated with Type II errors in analyses of this type, i.e., not noting a trend and consequently not acting on that trend, an emphasis is placed on limiting Type II errors and less emphasis is placed on Type I errors. Decreasing β, however, correspondingly increases α— the probability of Type I errors. The level of significance is therefore increased to $\alpha = 0.10$ rather than using $\alpha = 0.05$ used for the analyses mentioned earlier. The confidence level is accordingly set at 90 percent –– $100*(1-\alpha)$.

Increasing α simultaneously reduces β — the probability that a difference in the distributions or a trend will be erroneously missed. The probability of Type I and Type II errors (α and β) is simultaneously reduced through the pooling of two consecutive fiscal years of data and by eliminating known outside variants, e.g., facility complexity. Therefore, by applying a 90 percent confidence level on carefully selected and pooled data, trends can be spotted, and acted upon, as soon as possible while maintaining a reasonable limit on Type I errors.

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FY 1997 ACSEP Report Feedback Information

In a constant effort to improve the Aircraft Certification System Evaluation Program (ACSEP), you are asked to provide any relevant feedback to the attached report. This feedback could include views for additional areas of analysis; clarification of subject matter, data, and/or analysis; or general comments or remarks. We appreciate your input.

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